CONSENSUS STATEMENT

Anthrax as a Biological Weapon
Medical and Public Health Management

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Objective To develop consensus-based recommendations for measures to be taken by medical and public health professionals following the use of anthrax as a biological weapon against a civilian population.

Participants The working group included 21 representatives from staff of major academic medical centers and research, government, military, public health, and emergency management institutions and agencies.

Evidence MEDLINE databases were searched from January 1966 to April 1998, using the Medical Subject Headings *anthrax*, *Bacillus anthracis*, *biological weapon*, *biological terrorism*, *biological warfare*, and *biowarfare*. Review of references identified by this search led to identification of relevant references published prior to 1966. In addition, participants identified other unpublished references and sources.

Consensus Process The first draft of the consensus statement was a synthesis of information obtained in the formal evidence-gathering process. Members of the working group provided formal written comments which were incorporated into the second draft of the statement. The working group reviewed the second draft on June 12, 1998. No significant disagreements existed and comments were incorporated into a third draft. The fourth and final statement incorporates all relevant evidence obtained by the literature search in conjunction with final consensus recommendations supported by all working group members.

Conclusions Specific consensus recommendations are made regarding the diagnosis of anthrax, indications for vaccination, therapy for those exposed, postexposure prophylaxis, decontamination of the environment, and additional research needs.

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OF THE NUMEROUS BIOLOGICAL agents that may be used as weapons, the Working Group on Civilian Biodefense has identified a limited number of organisms that could cause disease and deaths in sufficient numbers to cripple a city or region. Anthrax is one of the most serious of these diseases.

High hopes were once vested in the Biological Weapons and Toxins Convention, which prohibited offensive biological weapons research or production and was signed by most countries. However, Iraq and the former Soviet Union, both signatories of the convention, have subsequently acknowledged having offensive biowarfare programs; a number of other countries are believed to have such programs, as have some autonomous terrorist groups. The possibility of a terrorist attack using bioweapons would be especially difficult to predict, detect, or prevent, and thus, it is among the most feared terrorist scenarios.[1]

Biological agents have seldom been dispersed in aerosol form, the exposure mode most likely to inflict widespread disease. Therefore, historical experience provides little information about the potential impact of a biological attack or the possible efficacy of postattack measures such as vaccination, antibiotic therapy, or quarantine. Policies and strategies must therefore rely on interpretation and extrapolation from an incomplete knowledge base. The Working Group on Civilian Biodefense reviewed the available literature and expertise and developed consensus recommendations for medical and public health measures to be taken following such an attack.

CONSENSUS METHODS

The working group comprised 21 representatives from academic medical cen-

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The first draft of the working group's consensus statement was the result of synthesis of information obtained in the formal evidence-gathering process. Members of the working group were asked to make formal written comments on this first draft of the document in May 1998. Suggested revisions were incorporated into the second draft of the statement. The working group was convened to review the second draft of the statement on June 12, 1998, at the Johns Hopkins Center for Civilian Biodefense Studies, Baltimore, Md. Consensus recommendations were made; no significant disagreements existed at the conclusion of this meeting. The third draft incorporated changes suggested at the conference and working group members had an additional opportunity to review the draft and suggest final revisions. The final statement incorporates all relevant evidence obtained by the literature search in conjunction with final consensus recommendations supported by all working group members. Funding for the development of the working group consensus statement was primarily provided by each representative's institution or agency. The Office of Emergency Preparedness, Department of Health and Human Services (DHHS), provided travel funds for 4 members of the group.

The assessment and recommendations provided herein represent the best professional judgment of the working group based on data and expertise currently available. The conclusions and recommendations need to be regularly reassessed as new information becomes available.

HISTORY OF CURRENT THREAT

For centuries, anthrax has caused disease in animals and, uncommonly, serious illness in humans throughout the world.[2] Research on anthrax as a biological weapon began more than 80 years ago.[3] Today, at least 17 nations are believed to have offensive biological weapons programs[4]; it is uncertain how many are working with anthrax. Iraq has acknowledged producing and weaponizing anthrax.[5]

Most experts concur that the manufacture of a lethal anthrax aerosol is beyond the capacity of individuals or groups without access to advanced biotechnology. However, autonomous groups with substantial funding and contacts may be able to acquire the required materials for a successful attack. One terrorist group, Aum Shinrikyo, responsible for the release of sarin in a Tokyo, Japan, subway station in 1995,[6] dispersed aerosols of anthrax and botulism throughout Tokyo on at least 8 occasions. For unclear reasons, the attacks failed to produce illness.[7]

The accidental aerosolized release of anthrax spores from a military microbiology facility in Sverdlovsk in the former Soviet Union in 1979 resulted in at least 79 cases of anthrax infection and 68 deaths and demonstrated the lethal potential of anthrax aerosols.[8] An anthrax aerosol would be odorless and invisible following release and would have the potential to travel many kilometers before disseminating.[9,10] Evidence suggests that following an outdoor aerosol release, persons indoors could be exposed to a similar threat as those outdoors.[11]

In 1970, a World Health Organization (WHO) expert committee estimated that casualties following the theoretical aircraft release of 50 kg of anthrax over a developed urban population of 5 million would be 250 000, 100 000 of whom would be expected to die without treatment.[9] A 1993 report by the US Congressional Office of Technology Assessment estimated that between 130 000 and 3 million deaths could follow the aerosolized release of 100 kg of anthrax spores upwind of the Washington, DC, area—lethality matching or exceeding that of a hydrogen bomb.[12] An economic model developed by the Centers for Disease Control and Prevention (CDC) suggested a cost of $26.2 billion per 100 000 persons exposed.[13]

EPIDEMIOLOGY

Naturally occurring anthrax is a disease acquired following contact with anthrax-infected animals or anthrax-contaminated animal products. The disease most commonly occurs in herbivores, which are infected by ingesting spores from the soil. Large anthrax epizootics in herbivores have been reported; during a 1945 outbreak in Iran, 1 million sheep died.[14] Animal vaccination programs have reduced drastically the animal mortality from the disease.[15] However, anthrax spores continue to be documented in soil samples from throughout the world.[16-18]

In humans, 3 types of anthrax infection occur: inhalational, cutaneous, and gastrointestinal. Naturally occurring inhalational anthrax is now a rare cause of human disease. Historically, wool sorters at industrial mills were at highest risk. Only 18 cases were reported in the United States from 1900 to 1978, with the majority occurring in special-risk groups, including goat hair mill or goatskin workers and wool or tannery workers. Two of the 18 cases were laboratory associated.[19]

Cutaneous anthrax is the most common naturally occurring form, with an estimated 2000 cases reported annually.[18] Disease typically follows exposure to anthrax-infected animals. In the United States, 224 cases of cutaneous anthrax were reported between 1944 and 1994.[20] The largest reported epidemic occurred in Zimbabwe between 1979 and 1985, when more than 10 000 human cases of anthrax were reported, nearly all of them cutaneous.[21]

Gastrointestinal anthrax is uncommonly reported.[18,22,23] However, gastrointestinal outbreaks have been reported

in Africa and Asia.[24] Gastrointestinal anthrax follows ingestion of insufficiently cooked contaminated meat and includes 2 distinct syndromes, oral-pharyngeal and abdominal.[22,24-27] In 1982, there were 24 cases of oral-pharyngeal anthrax in a rural northern Thailand outbreak following the consumption of contaminated buffalo meat.[24] In 1987, there were 14 cases of gastrointestinal anthrax reported in northern Thailand with both oral-pharyngeal and abdominal disease occurring.[25]

No case of inhalational anthrax has been reported in the United States since 1978,[19,20] making even a single case a cause for alarm today. As was demonstrated at Sverdlovsk in 1979, inhalational anthrax is expected to account for most morbidity and essentially all mortality following the use of anthrax as an aerosolized biological weapon.[8,28] In the setting of an anthrax outbreak resulting from an aerosolized release, cutaneous anthrax would be less common than inhalational anthrax, easier to recognize, simpler to treat, and associated with a much lower mortality. In the Sverdlovsk experience, there were no deaths in patients developing cutaneous anthrax.[8] There is little information available about the risks of direct contamination of food or water with anthrax spores. Although human infections have been reported, experimental efforts to infect primates by direct gastrointestinal instillation of anthrax spores have not been successful.[29]

MICROBIOLOGY

Bacillus anthracis derives from the Greek word for coal, *anthrakis*, because the disease causes black, coal-like skin lesions. *Bacillus anthracis* is an aerobic, gram-positive, spore-forming, nonmotile *Bacillus* species. The nonflagellated vegetative cell is large (1-8 µm in length, 1-1.5 µm in breadth). Spore size is approximately 1 µm. Spores grow readily on all ordinary laboratory media at 37°C, with a "jointed bamboo-rod" cellular appearance and a unique "curled-hair" colonial appearance, and display no hemolysis on sheep agar (FIGURE 1). This cellular and colonial morphology theoretically should make its identification by an experienced microbiologist straightforward, although few practicing microbiologists outside the veterinary community have seen anthrax colonies other than in textbooks.[30]

Anthrax spores germinate when they enter an environment rich in amino acids, nucleosides, and glucose, such as that found in the blood or tissues of an animal or human host. The rapidly multiplying vegetative anthrax bacilli, on the contrary, will only form spores after local nutrients are exhausted, such as when anthrax-infected body fluids are exposed to ambient air.[16,17] Full virulence requires the presence of both an antiphagocytic capsule and 3 toxin components (ie, protective antigen, lethal factor, and edema factor).[30] Vegetative bacteria have poor survival outside of an animal or human host; colony counts decline to undetectable within 24 hours following inoculation into water.[17] This contrasts with the environmentally hardy properties of the *B anthracis* spore, which can survive for decades.[30]

PATHOGENESIS AND CLINICAL MANIFESTATIONS

Inhalational Anthrax

Inhalational anthrax follows deposition of spore-bearing particles of 1 to 5 µm into alveolar spaces.[31,32] Macrophages ingest the spores, some of which undergo lysis and destruction. Surviving spores are transported via lymphatics to mediastinal lymph nodes, where germination may occur up to 60 days later.[28,29,33] The process responsible for the delayed transformation of spores to vegetative cells is poorly understood but well documented. In Sverdlovsk, cases occurred from 2 to 43 days after exposure.[8] In experimental monkeys, fatal disease occurred up to 58 days[29] and 98 days[34] after exposure. Viable spores have been demonstrated in the mediastinal lymph nodes of monkeys 100 days after exposure.[35]

Once germination occurs, disease follows rapidly. Replicating bacteria release toxins leading to hemorrhage, edema, and necrosis.[23,36] In experimental animals, once toxin production has reached critical threshold, death occurs even if sterility of the bloodstream is achieved with antibiotics.[19] Based on primate data, it has been estimated that for humans the LD 50 (lethal dose sufficient to kill 50% of persons exposed to it) is 2500 to 55 000 inhaled anthrax spores.[37]

The term *inhalational anthrax* reflects the nature of acquisition of the disease. The term *anthrax pneumonia* is misleading. Typical bronchopneumonia does not occur. Postmortem pathological study of patients who died because of inhalational anthrax in Sverdlovsk showed hemorrhagic thoracic lymphadenitis and hemorrhagic mediastinitis in all patients. In up to half of the patients, hemorrhagic meningitis also was seen. No patients who underwent autopsy had evidence of a bronchoalveolar pneumonic process, although 11 of 42 patients undergoing autopsy had evidence of a focal, hemorrhagic, necrotizing pneumonic lesion analogous to the Ghon complex associated with tuberculosis.[36] These findings are consistent with other human case series and experimentally induced inhalational anthrax in animals.[33,34,40]

Early diagnosis of inhalational anthrax would be difficult and would require a high index of suspicion. Clinical information is available from only some of the 18 cases reported in the United States in this century and from the limited available information from Sverdlovsk. The clinical presentation has been described as a 2-stage illness. Pa-

Figure 1. Gram Stain of *Bacillus anthracis*

Gram-positive anthrax bacilli in a peripheral blood smear from a rhesus monkey that died of inhalational anthrax. Reprinted with permission from Zajtchuk and Bellamy.[23]

tients first developed a spectrum of nonspecific symptoms, including fever, dyspnea, cough, headache, vomiting, chills, weakness, abdominal pain, and chest pain.[8,19] Signs of illness and laboratory studies were nonspecific. This stage of illness lasted from hours to a few days. In some patients, a brief period of apparent recovery followed. Other patients progressed directly to the second, fulminant stage of illness.[2,19,41]

This second stage developed abruptly, with sudden fever, dyspnea, diaphoresis, and shock. Massive lymphadenopathy and expansion of the mediastinum led to stridor in some cases.[42,43] A chest radiograph most often showed a widened mediastinum consistent with lymphadenopathy (FIGURE 2).[42] Up to half of patients developed hemorrhagic meningitis with concomitant meningismus, delirium, and obtundation. In this second stage of illness, cyanosis and hypotension progress rapidly; death sometimes occurs within hours.[2,19,41]

The mortality rate of occupationally acquired cases in the United States is 89%, but the majority of cases occurred before the development of critical care units and, in some cases, before the advent of antibiotics.[10] At Sverdlovsk, it is reported that 68 of the 79 patients with inhalational anthrax died, although the reliability of the diagnosis in the survivors is questionable.[8] Patients who had onset of disease 30 or more days after release of organisms had a higher reported survival rate compared with those with earlier disease onset. Antibiotics, antianthrax globulin, and vaccine were used to treat some residents in the affected area some time after exposure, but which patients received these interventions and when is not known. In fatal cases, the interval between onset of symptoms and death averaged 3 days. This is similar to the disease course and case fatality rate in untreated experimental monkeys, which have developed rapidly fatal disease even after a latency as long as 58 days.[28]

Modern mortality rates in the setting of contemporary medical and supportive therapy might be lower than those reported historically. However, the 1979 Sverdlovsk experience is not instructive. Although antibiotics, antianthrax globulin, corticosteroids, and mechanical ventilation were used, individual clinical records have not been made public.[8] It is also uncertain if the *B anthracis* strain to which patients were exposed was susceptible to the predominant antibiotics that were used during the outbreak.

Physiological sequelae of severe anthrax infection in animal models have been described as hypocalcemia, profound hypoglycemia, hyperkalemia, depression and paralysis of respiratory center, hypotension, anoxia, respiratory alkalosis, and terminal acidosis.[44,45] Those animal studies suggest that in addition to the rapid administration of antibiotics, survival might improve with vigilant correction of electrolyte disturbances and acid-base imbalance, glucose infusion, and early mechanical ventilation and vasopressor administration.

Figure 2. Chest Radiograph of a Patient With Inhalational Anthrax

Chest radiograph of a 51-year-old laborer with occupational exposure to airborne anthrax spores taken on day 2 of illness. Lobulated mediastinal widening (arrowheads) is present, consistent with lymphadenopathy, with a small parenchymal infiltrate at the left lung base. Reprinted with permission from Zajtchuk and Bellamy.[29]

Cutaneous Anthrax

Cutaneous anthrax occurs following the deposition of the organism into skin with previous cuts or abrasions especially susceptible to infection.[21,46] Areas of exposed skin, such as arms, hands, face, and neck, are the most frequently affected. There are no data to suggest the possibility of a prolonged latency period in cutaneous anthrax. In Sverdlovsk, cutaneous cases occurred only as late as 12 days after the original aerosol release.[8] After the spore germinates in skin tissues, toxin production results in local edema (FIGURE 3). An initially pruritic macule or papule enlarges into a round ulcer by the second day. Subsequently, 1- to 3-mm vesicles may appear, which discharge clear or serosanguinous fluid containing numerous organisms on Gram stain. As shown in Figure 3, development of a painless, depressed, black eschar follows, often associated with extensive local edema. The eschar dries, loosens, and falls off in the next 1 to 2 weeks, most often leaving no permanent scar. Lymphangitis and painful lymphadenopathy can occur with associated systemic symptoms. Although antibiotic therapy does not appear to change the course of eschar formation and heal-

Figure 3. Cutaneous Anthrax

Left, Forearm lesion on day 7 of illness shows vesiculation and ulceration of the initial macular or papular anthrax skin lesion. Right, Eschar of the neck on day 15 of illness is typical of the last stage of the lesion before it resolves over 1 to 2 weeks. Reprinted with permission from Binford CH, Connor DH, eds. *Pathology of Tropical and Extraordinary Diseases*. Vol 1. Washington, DC: Armed Forces Institute of Pathology; 1976:119. AFIP negative 71-1290-2.

ing, it does decrease the likelihood of systemic disease. Without antibiotic therapy, the mortality rate has been reported to be as high as 20%; with antibiotics, death due to cutaneous anthrax is rare.[2]

Gastrointestinal Anthrax

Gastrointestinal anthrax occurs following deposition and subsequent germination of spores in the upper or lower gastrointestinal tract. The former results in the oral-pharyngeal form of disease.[24-26] An oral or esophageal ulcer leads to development of regional lymphadenopathy, edema, and sepsis.[24-26] The latter results in primary intestinal lesions occurring predominantly in the terminal ileum or cecum,[38] presenting initially with nausea, vomiting, and malaise and progressing rapidly to bloody diarrhea, acute abdomen, or sepsis.[22] Massive ascites has occurred in some cases of gastrointestinal anthrax.[27] Advanced infection may appear similar to the sepsis syndrome occurring in either inhalational or cutaneous anthrax.[2] Some authors suggest that aggressive medical intervention such as would be recommended for inhalational anthrax may reduce mortality, although, given the difficulty of early diagnosis, mortality almost inevitably would be high.[2,22]

DIAGNOSIS

Given the rarity of anthrax infection and the possibility that early cases are a harbinger of a larger epidemic, the first suspicion of an anthrax illness must lead to immediate notification of the local or state health department, local hospital epidemiologist, and local or state health laboratory. By this mechanism, definitive tests can be arranged rapidly through a reference laboratory and, as necessary, the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Md.

The first evidence of a clandestine release of anthrax as a biological weapon most likely will be patients seeking medical treatment for symptoms of inhalational anthrax. The sudden appearance of a large number of patients in a city or region with an acute-onset flulike illness and case fatality rates of 80% or more, with nearly half of all deaths occurring within 24 to 48 hours, is highly likely to be anthrax or pneumonic plague (TABLE 1). Currently, there are no effective atmospheric warning systems to detect an aerosol cloud of anthrax spores.[17]

Table 1. Diagnosis of Inhalational Anthrax Infection

Epidemiology	Sudden appearance of multiple cases of severe flulike illness with fulminant course and high mortality
Diagnostic studies	Chest radiograph: widened mediastinum
	Peripheral blood smear: gram-positive bacilli on unspun smear
Microbiology	Blood culture growth of large gram-positive bacilli with preliminary identification of *Bacillus* species
Pathology	Hemorrhagic mediastinitis, hemorrhagic thoracic lymphadenitis, hemorrhagic meningitis

Rapid diagnostic tests for diagnosing anthrax, such as enzyme-linked immunosorbent assay for protective antigen and polymerase chain reaction, are available only at national reference laboratories. Given the limited availability of these tests and the time required to dispatch specimens and perform assays, rapid diagnostic testing would be primarily for confirmation of diagnosis and determining in vitro susceptibility to antibiotics. In addition, these tests will be used in the investigation and management of anthrax hoaxes, such as the series occurring in late 1998.[40] They would also be of value should suspicious materials in the possession of a terrorist be identified as possibly containing anthrax.

If only small numbers of cases present contemporaneously, the clinical similarity of early inhalational anthrax to other acute respiratory tract infections may delay initial diagnosis for some days. However, diagnosis of anthrax could soon become apparent through the astute recognition of an unusual radiological finding, identification in the microbiology laboratory, or recognition of specific pathologic findings. A widened mediastinum on chest radiograph (Figure 2) in a previously healthy patient with evidence of overwhelming flulike illness is essentially pathognomonic of advanced inhalational anthrax and should prompt immediate action.[23,42] Although treatment at this stage would be unlikely to alter the outcome of illness in the patient concerned, it might lead to earlier diagnosis in others.

Microbiologic studies can also demonstrate *B anthracis* and may be the means for initial detection of an outbreak. The bacterial burden may be so great in advanced infection that bacilli are visible on Gram stain of unspun peripheral blood, as has been demonstrated in primate studies (Figure 1). While this is a remarkable finding that would permit an astute clinician or microbiologist to make the diagnosis, the widespread use of automated cell-counter technology in diagnostic laboratories makes this unlikely.[41]

The most useful microbiologic test is the standard blood culture, which should show growth in 6 to 24 hours. If the laboratory has been alerted to the possibility of anthrax, biochemical testing and review of colonial morphology should provide a preliminary diagnosis 12 to 24 hours later. Definitive diagnosis would require an additional 1 to 2 days of testing in all but a few national reference laboratories. It should be noted, however, that if the laboratory has not been alerted to the possibility of anthrax, *B anthracis* may not be correctly identified. Routine laboratory procedures customarily identify a *Bacillus* species from a blood culture approximately 24 hours after growth, but most laboratories do not further identify *Bacillus* species unless specifically requested to do so. In the United States, the isolation of *Bacillus* species most often represents growth of *Bacillus cereus*. The laboratory and clinician must determine whether its isolation represents specimen contamination.[49] There have been no *B anthracis* bloodstream infections reported for more than 20

years. However, given the possibility of anthrax being used as a weapon and the importance of early diagnosis, it would be prudent for laboratory procedures to be modified so that *B anthracis* is excluded after identification of a *Bacillus* species bacteremia.

Sputum culture and Gram stain are unlikely to be diagnostic, given the lack of a pneumonic process.[30] If cutaneous anthrax is suspected, a Gram stain and culture of vesicular fluid will confirm the diagnosis.

A diagnosis of inhalational anthrax also might occur at postmortem examination following a rapid, unexplained terminal illness. Thoracic hemorrhagic necrotizing lymphadenitis and hemorrhagic necrotizing mediastinitis in a previously healthy adult are essentially pathognomonic of inhalational anthrax.[38,43] Hemorrhagic meningitis should also raise strong suspicion of anthrax infection.[23,38,43,50] Despite pathognomonic features of anthrax on gross postmortem examination, the rarity of anthrax makes it unlikely that a pathologist would immediately recognize these findings. If the case were not diagnosed at gross examination, additional days would likely pass before microscopic slides would be available to suggest the disease etiology.

VACCINATION

The US anthrax vaccine, an inactivated cell-free product, was licensed in 1970 and is produced by Bioport Corp, Lansing, Mich (formerly called the Michigan Biologic Products Institute). The vaccine is licensed to be given in a 6-dose series and has recently been mandated for all US military active- and reserve-duty personnel.[51] The vaccine is made from the cell-free filtrate of a nonencapsulated attenuated strain of *B anthracis*.[52] The principal antigen responsible for inducing immunity is the protective antigen.[18,23] A similar vaccine has been shown in 1 small placebo-controlled human trial to be efficacious against cutaneous anthrax.[53] As of March 1, 1999, approximately 590 000 doses of anthrax vaccine have been administered to US Armed Forces (Gary Strawder, Department of Defense, Falls Church, Va, oral communication, April 1999); no serious adverse events have been causally related (Miles Braun, Food and Drug Administration, Rockville, Md, written communication, April 1999). In a study of experimental monkeys, inoculation with this vaccine at 0 and 2 weeks was completely protective against an aerosol challenge at 8 and 38 weeks and 88% effective at 100 weeks.[54]

A human live attenuated vaccine is produced and used in countries of the former Soviet Union.[55] In the Western world, live attenuated vaccines have been considered unsuitable for use in humans.[55]

Current vaccine supplies are limited and the US production capacity is modest. It will be years before increased production efforts can make available sufficient quantities of vaccine for civilian use. However, even if vaccine were available, populationwide vaccination would not be recommended at this time, given the costs and logistics of a large-scale vaccination program and the unlikely occurrence of a bioterrorist attack in any given community. Vaccination of some essential service personnel should be considered if vaccine becomes available. Postexposure vaccination following a biological attack with anthrax would be recommended with antibiotic administration to protect against residual retained spores, if vaccine were available.

THERAPY

Recommendations regarding antibiotic and vaccine use in the setting of a biological anthrax attack are conditioned by a limited number of studies in experimental animals, current understanding of antibiotic resistance patterns, and the possible requirement to treat large numbers of casualties. A number of possible therapeutic strategies have yet to be fully explored experimentally or submitted for approval to the FDA. For these reasons, the working group offers consensus recommendations based on the best available evidence. The recommendations do not represent uses currently approved by the FDA or an official position on the part of any of the federal agencies whose scientists participated in these discussions and will need to be revised as further relevant information becomes available.

Given the rapid course of symptomatic inhalational anthrax, early antibiotic administration is essential. A delay of antibiotic treatment for patients with anthrax infection even by hours may substantially lessen chances for survival.[56,57] Given the difficulty in achieving rapid microbiologic diagnosis of anthrax, all persons with fever or evidence of systemic disease in an area where anthrax cases are occurring should be treated for anthrax until the disease is excluded.

There are no clinical studies of the treatment of inhalational anthrax in humans. Thus, antibiotic regimens commonly recommended for empirical treatment of sepsis have not been studied in this setting. In fact, natural strains of *B anthracis* are resistant to many of the antibiotics used in these empirical regimens, such as those of the extended-spectrum cephalosporins.[58,59] Most naturally occurring anthrax strains are sensitive to penicillin, and penicillin historically has been the preferred therapy for the treatment of anthrax. Penicillin is approved by the FDA for this indication,[41,56,57] as is doxycycline.[60] In studies of small numbers of monkeys infected with susceptible strains of *B anthracis*, oral doxycycline has proved efficacious.[41]

Doxycycline is the preferred option from the tetracycline class of antibiotics because of its proven efficacy in monkey studies and its ease of administration. Other members of this class of antibiotics are suitable alternatives. Although treatment of anthrax infection with ciprofloxacin has not been studied in humans, animal models suggest excellent efficacy.[28,41,61] In vitro data suggest that other fluoroquinolone antibiotics would have equivalent efficacy in treating anthrax infection, although no animal data exist for fluoroquinolones other than ciprofloxacin.[59]

Reports have been published of a *B anthracis* vaccine strain that has been engineered by Russian scientists to resist the tetracycline and penicillin classes of antibiotics.[62] Although the engineering of quinolone-resistant *B anthracis* may also be possible, to date there have been no published accounts of this.

Balancing considerations of efficacy with concerns regarding resistance, the working group recommends that ciprofloxacin or other fluoroquinolone therapy be initiated in adults with presumed inhalational anthrax infection. Antibiotic resistance to penicillin- and tetracycline-class antibiotics should be assumed following a terrorist attack until laboratory testing demonstrates otherwise. Once the antibiotic susceptibility of the *B anthracis* strain of the index case has been determined, the most widely available, efficacious, and least toxic antibiotic should be administered to patients and persons requiring postexposure prophylaxis.

In a contained casualty setting (a situation in which a modest number of patients require therapy), the working group recommends intravenous antibiotic therapy, as shown in TABLE 2. If the number of persons requiring therapy is sufficiently high (ie, a mass casualty setting), the working group recognizes that intravenous therapy will no longer be possible for reasons of logistics and/or exhaustion of equipment and antibiotic supplies, and oral therapy will need to be used (TABLE 3). The threshold number of cases at which parenteral therapy becomes impossible depends on a variety of factors, including local and regional health care resources.

In experimental animals, antibiotic therapy during anthrax infection has prevented development of an immune response.[28,62] This suggests that even if the antibiotic-treated patient survives anthrax infection, risk for recurrence remains for at least 60 days because of the possibility of delayed germination of spores. Therefore, the working group recommends that antibiotic therapy be continued for 60 days, with oral therapy replacing intravenous therapy as soon as a patient's clinical condition improves. If vaccine were to become widely available, postexposure vaccination in patients being treated for anthrax infection might permit the duration of antibiotic administration to be shortened to 30 to 45 days, with concomitant administration of 3 doses of anthrax vaccine at 0, 2, and 4 weeks.

The treatment of cutaneous anthrax historically has been with oral penicillin. The working group recommends that oral fluoroquinolone or tetracycline antibiotics as well as amoxicillin in the adult dosage schedules described in Tables 2 and 3 would be suitable alternatives if antibiotic susceptibility is proved. Although previous guidelines have suggested treating cutaneous anthrax for 7 to 10 days,[23,49] the working group recommends treatment for 60 days in the setting of bioterrorism, given the presumed exposure to the primary aerosol. Treatment of cutaneous anthrax generally prevents progression to systemic disease, although it does not prevent the formation and evolution of the eschar. Topical therapy is not useful.[2]

Other antibiotics effective against *B anthracis* in vitro include chloramphenicol, erythromycin, clindamycin, extended-spectrum penicillins, macrolides, aminoglycosides, vancomycin hydrochloride, cefazolin, and other first-generation cephalosporins.[58,59,64] The efficacy of these antibiotics has not been tested in humans or animal studies. The working group recommends the use of these antibiotics only if the previously cited antibiotics are unavailable or if the strain is otherwise antibiotic resistant. Natural resistance of *B anthracis* strains exists against sulfamethoxazole, trimethoprim, cefuroxime, cefotaxime sodium, aztreonam, and ceftazidime.[58,59,64] Therefore, these antibiotics should not be used in the treatment or prophylaxis of anthrax infection.

Postexposure Prophylaxis

Guidelines regarding which populations would require postexposure prophylaxis following the release of anthrax as a biological weapon would need to be developed quickly by state and local health departments in consultation with national experts. These decisions require estimates of the timing and location of the exposure and the relevant weather conditions in an outdoor release.[65] Ongoing monitoring of cases would be needed to define the

Table 2. Working Group Recommendations for Medical Therapy for Patients With Clinically Evident Inhalational Anthrax Infection in the Contained Casualty Setting[28,41,46,62,63]*

	Initial Therapy†	Optimal Therapy if Strain Is Proven Susceptible	Duration, d‡
Adults	Ciprofloxacin, 400 mg intravenously every 12 h	Penicillin G, 4 million U intravenously every 4 h Doxycycline, 100 mg intravenously every 12 h§	60
Children‖	Ciprofloxacin, 20-30 mg/kg per day intravenously divided into 2 daily doses, not to exceed 1 g/d	Age <12 y: penicillin G, 50 000 U/kg intravenously every 6 h Age ≥12 y: penicillin G, 4 million U intravenously every 4 h	60
Pregnant women¶	Same as for nonpregnant adults		
Immunosuppressed persons	Same as for nonimmunosuppressed adults and children		

*Most recommendations are based on animal studies or in vitro studies and are not approved by the US Food and Drug Administration (FDA). These recommendations are not FDA approved but were reached by consensus of the working group. See text for explanations and alternatives.
†In vitro studies suggest ofloxacin, 400 mg intravenously every 12 hours, or levofloxacin, 500 mg intravenously every 24 hours, could be substituted for ciprofloxacin.
‡Oral antibiotics should be substituted for intravenous antibiotics as soon as clinical condition improves.
§In vitro studies suggest tetracycline could be substituted for doxycycline.
‖Doxycycline could also be used. For children heavier than 45 kg, use adult dosage. For children 45 kg or lighter, use 2.5 mg/kg doxycycline intravenously every 12 hours. Refer to management of pediatric population in text for details.
¶Refer to section on management of pregnant women in text for details.

high-risk areas, direct follow-up, and guide the addition or deletion of groups to receive postexposure prophylaxis.

There are no FDA-approved postexposure antibiotic regimens following exposure to an anthrax aerosol. For postexposure prophylaxis, the working group recommends the same antibiotic regimen as that recommended for treatment of mass casualties; prophylaxis should be continued for 60 days (Table 3).

Management of Special Groups

Consensus recommendations for special groups as set forth herein reflect the clinical and evidence-based judgments of the working group and at this time do not necessarily correspond with FDA-approved use, indications, or labeling.

Children. It has been recommended that ciprofloxacin and other fluoroquinolones should not be used in children younger than 16 to 18 years because of a link to permanent arthropathy in adolescent animals and transient arthropathy in a small number of children.[50] However, balancing these risks against the risks of anthrax caused by an engineered antibiotic-resistant strain, the working group recommends that ciprofloxacin be used in the pediatric population for initial therapy or postexposure prophylaxis following an anthrax attack (Table 2). If antibiotic susceptibility testing allows, penicillin should be substituted for the fluoroquinolone.

As a third alternative, doxycycline could be used. The American Academy of Pediatrics has recommended that doxycycline not be used in children younger than 9 years because the drug has resulted in retarded skeletal growth in infants and discolored teeth in infants and children.[60] However, the serious risk of infection following an anthrax attack supports the consensus recommendation that doxycycline be used in children if antibiotic susceptibility testing, exhaustion of drug supplies, or allergic reaction preclude use of penicillin and ciprofloxacin.

In a contained casualty setting, the working group recommends that children receive intravenous antibiotics (Table 2). In a mass casualty setting and as postexposure prophylaxis, the working group recommends that children receive oral antibiotics (Table 3).

The US vaccine is licensed for use only in persons aged 18 to 65 years because studies to date have been conducted exclusively in this group.[51] No data exist for children, but based on experience with other inactivated vaccines, it is likely that the vaccine would be safe and effective.

Pregnant Women. Fluoroquinolones are not generally recommended during pregnancy because of their known association with arthropathy in adolescent animals and small numbers of children. Animal studies have discovered no evidence of teratogenicity related to ciprofloxacin, but no controlled studies of ciprofloxacin in pregnant women have been conducted. Balancing these possible risks against the concerns of anthrax due to engineered antibiotic-resistant strains, the working group recommends that ciprofloxacin be used in pregnant women for therapy and postexposure prophylaxis following an anthrax attack (Tables 2 and 3). No adequate controlled trials of penicillin or amoxicillin administration during pregnancy exist. However, the CDC recommends penicillin for the treatment of syphilis during pregnancy and amoxicillin as a treatment alternative for chlamydial infections during pregnancy.[60]

The working group recommends that pregnant women receive fluoroquinolones in the usual adult dosages. If susceptibility testing allows, intravenous penicillin in the usual adult dosages should be substituted for fluoroquinolones. As a third alternative, intravenous doxycycline could be used. The tetracycline class of antibiotics has been associated with both toxic effects in the liver in pregnant women and fetal toxic effects, including retarded skeletal growth.[60] Balancing the risks of anthrax infection with those associated with doxycycline use in pregnancy, the working group recommends that doxycycline be used in pregnant women for therapy and postexposure prophylaxis if antibiotic susceptibility testing, exhaustion of drug supplies, or allergic sensitivity preclude the use of penicillin and ciprofloxacin. If doxycycline is used in pregnant women, periodic liver function testing should be performed if possible.

Table 3. Working Group Recommendations for Medical Therapy for Patients With Clinically Evident Anthrax Infection in the Mass Casualty Setting or for Postexposure Prophylaxis*

	Initial Therapy†	Optimal Therapy if Strain Is Proven Susceptible	Duration, d
Adults	Ciprofloxacin, 500 mg by mouth every 12 h	Amoxicillin, 500 mg every 8 h Doxycycline, 100 mg by mouth every 12 h‡	60
Children§	Ciprofloxacin, 20-30 mg/kg per day by mouth divided into 2 daily doses, not to exceed 1 g/d	Weight ≥20 kg: amoxicillin, 500 mg by mouth every 8 h Weight <20 kg: amoxicillin, 40 mg/kg divided into 3 doses to be taken every 8 h	60
Pregnant women‖	Ciprofloxacin, 500 mg by mouth every 12 h	Amoxicillin, 500 mg by mouth every 8 h	60
Immunosuppressed persons	Same as for nonimmunosuppressed adults and children		

*Most recommendations are based on animal studies or in vitro studies and are not approved by the US Food and Drug Administration (FDA). These recommendations are not FDA approved but were reached by consensus of the working group. See text for explanations and alternatives.
†In vitro studies suggest ofloxacin, 400 mg by mouth every 12 hours, or levofloxacin, 500 mg by mouth every 24 hours, could be substituted for ciprofloxacin.
‡In vitro studies suggest tetracycline, 500 mg by mouth every 6 hours, could be substituted for doxycycline.
§Doxycycline could also be used. For children heavier than 45 kg, use adult dosage. For children 45 kg or lighter, use 2.5 mg/kg doxycycline by mouth every 12 hours. Refer to management of pediatric population in text for details.
‖Refer to management of pregnant population in text for details.

Ciprofloxacin (and other fluoroquinolones), penicillin, and doxycycline (and other tetracyclines) are each excreted in breast milk. Therefore, a breast-feeding woman should be treated or given prophylaxis with the same antibiotic as her infant based on what is most safe and effective for the infant (see pediatric guidelines herein) to minimize risk to the infant.

Immunosuppressed Persons. The antibiotic treatment or postexposure prophylaxis for anthrax among those who are immunosuppressed has not been studied in human or animal models of anthrax infection. Therefore, the working group consensus recommendation is to administer antibiotics as for immunocompetent adults and children (Tables 2 and 3).

INFECTION CONTROL

There are no data to suggest patient-to-patient transmission of anthrax occurs.[8,46] Thus, standard barrier isolation precautions are recommended for hospitalized patients with all forms of anthrax infection, but the use of high-efficiency particulate air filter masks or other measures for airborne protection are not indicated.[66] There is no need to immunize or provide prophylaxis to patient contacts (eg, household contacts, friends, coworkers) unless a determination is made that they, like the patient, were exposed to the aerosol at the time of the attack.

In addition to immediate notification of the hospital epidemiologist and state health department, the local hospital microbiology laboratories should be notified at the first indication of anthrax so that safe specimen processing under biosafety level 2 conditions can be undertaken.[41,67] A number of disinfectants used for standard hospital infection control, such as hypochlorite, are effective in cleaning environmental surfaces contaminated with infected bodily fluids.[17,66]

Proper burial or cremation of humans and animals who have died because of anthrax infection is important in preventing further transmission of the disease. Serious consideration should be given to cremation. Embalming of bodies could be associated with special risks.[66] If autopsies are performed, all related instruments and materials should be autoclaved or incinerated.[66] Animal transmission might occur if infected animal remains are not cremated or buried.[16,21]

Figure 4. Day of Onset of Inhalational Anthrax Following Sverdlovsk Accident

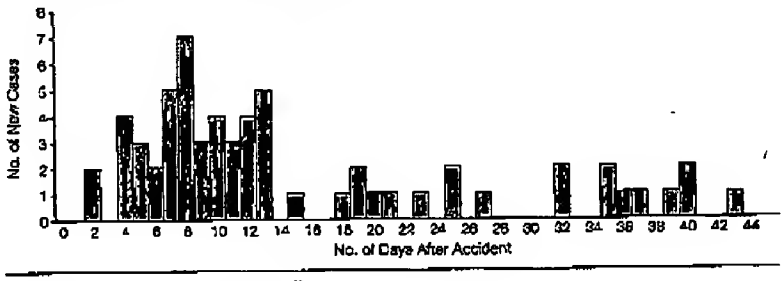

Figure is based on data from Guillemin.[68]

DECONTAMINATION

Recommendations regarding decontamination in the event of an intentional aerosolization of anthrax spores are based on evidence concerning aerosolization, anthrax spore survival, and environmental exposures at Sverdlovsk and among goat hair mill workers. The greatest risk to human health following an intentional aerosolization of anthrax spores occurs during the period in which anthrax spores remain airborne, called *primary aerosolization*. The duration for which spores remain airborne and the distance spores travel before they become noninfectious or fall to the ground is dependent on meteorological conditions and aerobiological properties of the dispersed aerosol.[8,63] Under circumstances of maximum survival and persistence, the aerosol would be fully dispersed within hours to 1 day at most, well before the first symptomatic cases would be seen. Following the discovery that a bioweapon has been used, anthrax spores may be detected on environmental surfaces using rapid assay kits or culture, but they provide no indication as to the risk of reaerosolization.

The risk that anthrax spores might pose to public health after the period of primary aerosolization can be inferred from the Sverdlovsk experience, investigations in animal hair processing plants, and modeling analyses by the US Army. At Sverdlovsk, new cases of inhalational anthrax developed as late as 43 days after the presumed date of release, but none occurred during the months and years afterward.[68] Some have questioned whether any of those cases with onset of disease beyond 7 days might have represented illness following resuspension of spores from the ground or other surfaces, a process that has been called *secondary aerosolization*. While it is impossible to state with certainty that secondary aerosolizations did not occur, it appears unlikely. It should be noted that few efforts were made to decontaminate the environment after the accident and only 47 000 of the city's 1 million inhabitants were vaccinated.[8] The epidemic curve (FIGURE 4) is typical for a common-source epidemic, and it is possible to account for virtually all patients having been within the area of the plume on the day of the accident. Moreover, if secondary aerosolization had been important, new cases almost certainly would have continued for a period well beyond the observed 43 days.

Although persons working with animal hair or hides are known to be at increased risk of developing inhalational or cutaneous anthrax, surprisingly few of those exposed in the United States have developed disease. During the first half of this century, a significant number of goat hair mill workers were likely exposed to aerosolized spores. Mandatory vaccination became a requirement

for working in goat hair mills only in the 1960s. Meanwhile, many unvaccinated person-years of high-risk exposure had occurred, but only 13 cases of inhalational anthrax were reported.[19,44] One study of environmental exposure was conducted at a Pennsylvania goat hair mill at which workers were shown to inhale up to 510 *B anthracis* particles of at least 5 µm in diameter per person per 8-hour shift. These concentrations of spores were constantly present in the environment during the time of this study,[44] but no cases of inhalational anthrax occurred.

Modeling analyses have been carried out by US Army scientists seeking to determine the risk of secondary aerosolization. One study concluded that there was no significant threat to personnel in areas contaminated by 1 million spores per square meter either from traffic on asphalt-paved roads or from a runway used by helicopters or jet aircraft.[69] A separate study showed that in areas of ground contaminated with 20 million *Bacillus subtilis* spores per square meter, a soldier exercising actively for a 3-hour period would inhale between 1000 and 15 000 spores.[70]

Much has been written about the technical difficulty of decontaminating an environment contaminated with anthrax spores. A classic case is the experience at Gruinard Island in the United Kingdom. During World War II, British military undertook explosives testing with anthrax spores on this island off the Scottish coast. Spores persisted and remained viable for 36 years following the conclusion of testing. Decontamination of the island occurred in stages, beginning in 1979 and ending in 1987, when the island was finally declared fully decontaminated. The total cost is unpublished, but materials required included 280 tons of formaldehyde and 2000 tons of seawater.[17,71]

If an environmental surface is proved to be heavily contaminated with anthrax spores in the immediate area of a spill or close proximity to the point of release of an anthrax aerosol, decontamination of that area may decrease the slight risk of acquiring anthrax by secondary aerosolization. However, decontamination of large urban areas or even a building following an exposure to an anthrax aerosol would be extremely difficult and is not indicated. Although the risk of disease caused by secondary aerosolization would be extremely low, it would be difficult to offer absolute assurance that there was not risk whatsoever. Postexposure vaccination, if vaccine were available, might be a possible intervention that could further lower the risk of anthrax infection in this setting.

In the setting of an announced alleged anthrax release, such as the series of anthrax hoaxes occurring in many areas of the United States in 1998,[48] any person coming in direct physical contact with a substance alleged to be anthrax should perform thorough washing of the exposed skin and articles of clothing with soap and water.[72] Further decontamination of directly exposed individuals or of others is not indicated. In addition, any person in direct physical contact with the alleged substance should receive postexposure antibiotic prophylaxis until the substance is proved not to be anthrax. If the alleged substance is proved to be anthrax, immediate consultation with experts at the CDC and USAMRIID should be obtained.

ADDITIONAL RESEARCH

To develop a maximally effective response to a bioterrorist incident involving anthrax, the medical community will require new knowledge of the organism, its genetics and pathogenesis, improved rapid diagnostic techniques, improved prophylactic and therapeutic regimens, and an improved second-generation vaccine.[57] A recently published Russian study indicates that genes transferred from the related *B cereus* can act to enable *B anthracis* to evade the protective effect of the live attenuated Russian vaccine in a rodent model.[73] Research is needed to determine the role of these genes with respect to virulence and ability to evade vaccine-induced immunity. Furthermore, the relevance of this finding for the US vaccine needs to be established. An accelerated vaccine development effort is needed to allow the manufacture of an improved second-generation product that requires fewer doses. Finally, an expanded knowledge base is needed regarding possible maximum incubation times after inhalation of spore-containing aerosols and optimal postexposure antibiotic regimens.

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Disclaimers: In many cases, the indication and dosages and other information are not consistent with current approved labeling by the US Food and Drug Administration (FDA). The recommendations on the use of drugs and vaccine for uses not approved by the FDA do not represent the official views of the FDA or of any of the federal agencies whose scientists participated in these discussions. Unlabeled uses of the products recommended are noted in the sections of this article in which these products are discussed. Where unlabeled uses are indicated, information used as the basis for the recommendation is discussed.

The views, opinions, assertions, and findings contained herein are those of the authors and should not be construed as official US Department of Defense or US Department of Army positions, policies, or decisions unless so designated by other documentation.

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RESEARCH LETTER

NIH Research Grants: Funding and Re-funding

To the Editor: National Institutes of Health (NIH) grants play an important role in the careers of the research faculty in medical schools. Given the importance of NIH funding in an academic career, we sought to determine several aspects of NIH funding that have, to the best of our knowledge, not been examined in detail. These are (1) the median length of time of NIH funding during the academic life of an individual, (2) the predictive value, for long-term funding, of receiving NIH funding at any given time, and (3) the effect of length of the unfunded period on the likelihood that an investigator will be subsequently funded.

Methods. We obtained the funding histories of individuals who were awarded any NIH grants in the index years 1972 and 1982, and tracked individual funding histories for 25 years and 15 years, respectively. Data consisted of the number of grants each individual received annually following the index year. A total of 1707 individuals received awards in 1972 and 1639 in 1982. Because of the nature of record keeping at the NIH, the precise length of each award was not available. Based on the historical experience of NIH funding, we assumed that the average length of an NIH award is 4 years.

Results. The mean number of awards obtained by individuals throughout their careers was 2.5 for the 1972 and 3.3 for the 1982 cohort; the median for both groups was 2.0. About 40% of individuals who obtain an NIH grant never received another for the rest of their careers.

The best predictor of future funding appears to be the number of grants garnered during a 10-year period. Thus, for both the 1972 and 1982 cohorts, we computed the proportion of individuals obtaining 1, 2, or more than 2 awards over a 10-year period from 1972 to 1981 or 1982 to 1991, respectively. The distribution of the individuals into these 3 categories was similar in the 2 cohorts: 39.0% vs 35.0%, 18.3% vs 22.0%, and 42.4% vs 42.0%, respectively. For individuals who only obtained 1 grant for the 10-year period (1972-1981 or 1982-1991), 92.5% and 93%, respectively, did not obtain any funding for the subsequent period until 1997. Of those who received 1 additional grant (or a total of 2 grants for the 10-year period), 72% did not obtain any subsequent funding until 1997. These 2 cohorts were in contrast with those who obtained more than 2 grants for the 10-year interval. Only 27% of these individuals failed to obtain a grant for the subsequent period.

Comment. The cumulative period of NIH funding appears to be rather brief for most individuals. Neither the possession of an NIH grant nor the apparent ability to acquire one based on prior research training or history predicts whether an individual will receive future grants.

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CORRECTIONS

Incorrect Equation: In the Original Contribution entitled "Empirical Evidence of Design-Related Bias in Studies of Diagnostic Tests" published in the September 15, 1999, issue of THE JOURNAL (1999;282:1061-1066), the equation was incorrect. On page 1063, the equation should have appeared:

$$\text{DOR} = \frac{\text{Sensitivity}}{(1 - \text{Sensitivity})} \div \frac{(1 - \text{Specificity})}{\text{Specificity}}$$

Incorrect Color Reproduction: In the Consensus Statement entitled "Anthrax as a Biological Weapon: Medical and Public Health Management" published in the May 12, 1999, issue of THE JOURNAL (1999;281:1735-1745), the color of the photomicrograph in Figure 1 on page 1727 was incorrectly reproduced. The correct image showing gram-positive anthrax bacilli in a peripheral blood smear from a rhesus monkey that died of inhalational anthrax is shown below, left. A second photomicrograph (lower magnification) of a gram stain of the peripheral blood of a rhesus monkey that died of inhalational anthrax is also shown below, right.

Figure. Gram Stains of *Bacillus anthracis*

Left, Reprinted with permission from Zajtchuk R, Bellamy RF, eds. *Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare*. Washington, DC: Office of the Surgeon General, US Dept of the Army; 1997.

2002

THE DECONTAMINATION OF ANTHRAX
AND OTHER BIOLOGICAL AGENTS

HEARING

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C O N T E N T S

Technology Policy, Executive Office of the President to Chairman Boehlert and Ranking Member Hall

''Evicting an Unwelcome Tenant: Anthrax,'' The New York Times, Tuesday, November 6, 2001

Page 8 PREV PAGE TOP OF DOC Segment 1 of 2 ''U.S. Officials Reorganize Strategy on Bioterrorism,'' The Washington Post, Thursday, November 8, 2001

''A Comparison of Decontamination Technologies for Biological Agent on Selected Commercial Surface Materials-Summary Report,'' Laurel E. O'Connor, U.S. Army Soldier and Biological Chemical Command, Aberdeen Proving Ground, Maryland, May 2001

THE DECONTAMINATION OF ANTHRAX AND OTHER BIOLOGICAL AGENTS

THURSDAY, NOVEMBER 8, 2001

House of Representatives,
Committee on Science,
Washington, DC.

The Committee met, pursuant to call, at 10:13 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Sherwood L. Boehlert (chairman of the committee) presiding.

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HEARING CHARTER

COMMITTEE ON SCIENCE

U.S. HOUSE OF REPRESENTATIVES

Page 9 PREV PAGE TOP OF DOC Segment 1 of 2 The Decontamination of Anthrax and

Other Biological Agents

THURSDAY, NOVEMBER 8, 2001

10:00 A.M.-12:00 P.M.

2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Thursday, November 8, 2001 the House Committee on Science will hold a hearing to receive testimony regarding the decontamination of anthrax and other biological agents from public facilities. Specifically, this hearing will explore the challenges of decontaminating civilian facilities, the experience gained by the U.S. Army in decontaminating property at Fort Detrick, and the potential of new decontamination technologies and methods.

Witnesses

The Committee will hear testimony from:

1. Dr. James Baker, Jr., Director of the Center for Biologic Nanotechnology and Professor of Internal Medicine, The University of Michigan, Ann Arbor, Michigan.

Page 10 PREV PAGE TOP OF DOC Segment 1 of 2 2. Mr. Manuel Barbeito

(retired), Chief of the Aerobiology Section, Agent Control Division, U.S. Army Biological Warfare Laboratories, Fort Detrick, Maryland.

3. Dr. Charles Haas, Professor of Environmental Engineering, Drexel University, Philadelphia, Pennsylvania.

4. Dr. Lynn Goldman, Professor of Environmental Health Sciences, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland.

Introduction

Ever since Bob Stevens was maliciously infected and subsequently died from inhalation anthrax in early October 2001, bioterrorism has become a household word. As of November 2, 2001, seventeen confirmed cases of anthrax infections have occurred, all in the eastern United States. The challenge facing our nation's scientific and defense community now is to prepare effective and safe methods to decontaminate buildings of infectious agents, not in military facilities, but in every day civilian buildings and workplaces.

As little as we know about the ways in which biological agent like anthrax can be spread through the U.S. mail system, we perhaps know even less about how to safely clean up civilian sites that have been contaminated. While several technologies exist that can effectively destroy biological agents in controlled experimental conditions, the decontamination of large buildings to allow people to return to work presents serious technical and scientific challenges that have not been the subject of extensive testing. This hearing is an attempt to shed light on what we know about the options for decontaminating biological agents, the gaps in our knowledge, and the most expeditious ways to learn what we must in order to deal effectively with the crisis at hand.

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Federal Efforts to Improve Response to Biological Contamination

Responsibility for biological weapons decontamination is divided. The Department of Defense (DoD) is responsible for the decontamination of defense-related facilities and the Environmental Protection Agency (EPA) is responsible for civilian-related sites. The EPA coordinates the response of State, local and other Federal agencies to emergencies involving hazardous materials or oil spills through a program authorized under the Clean Water Act and the Superfund law.

In the National Defense Authorization Act for FY 1997, Congress directed the Secretary of Defense to test and improve the response of all levels of government to emergencies involving biological and chemical weapons. As part of that effort, DoD initiated a joint program with the Department of Health and Human Services, the Federal Emergency Management Agency, the Federal Bureau of Investigation, EPA, and the Department of Energy. That group, the Biological Weapons Improved Response Program, identified serious gaps in our ability to respond to a biological attack.

Those gaps included deficiencies in our understanding of how to decontaminate a public building after a biological attack and how to determine when, or if, the building is clean enough for people to return. A 1998 review of decontamination technologies and protocols conducted for EPA by the private Institute for Defense Analysis concluded that there were no current protocols to decontaminate an office or workspace or an entire public building.

Options for Decontamination

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Methods to kill bacteria and other infectious agents in the production of pharmaceuticals, foodstuffs, and in microbiology laboratories are well

understood. However, decontamination of microbiological agents used in warfare or terrorism, especially in a domestic environment, presents entirely different challenges.

To be useful a decontaminant must be reactive, yet non-corrosive, safe to use on sensitive equipment like computers, effective on a broad spectrum of chemical and biological agents, and environmentally safe. In addition, it is preferable that such decontaminants be convenient to use and leave surfaces and materials clean. Unfortunately, while existing options for decontamination are effective against a wide variety of chemical and biological agents, many are slow and labor intensive, often damaging to equipment and other materials, difficult to use, and potentially dangerous to the environment and to people. In addition, many are inadequate for decontaminating large areas.

There are two general categories of methods for decontaminating biological and/or chemical agents–reactive gases and liquid solutions and foams:

Reactive gases and gas-like technologies–Entire rooms may be decontaminated by filling them with high concentrations of a chemically reactive gas, such as formaldehyde gas, ethylene dioxide, or chlorine dioxide. Gases have a presumed advantage over foams and liquids in that they are believed to be able to reach into every nook and cranny of a room. However, they can be extremely toxic and, if they escape, can pose greater safety concerns than liquid decontaminants.

Page 13 PREV PAGE TOP OF DOC Segment 1 Of 2 In general, these methods have been proven extremely effective in the controlled setting of the laboratory and in decontaminating smaller areas, but have not been tested in large civilian office buildings. Chlorine dioxide, the gas chosen to decontaminate the Hart Senate Office Building, has been used for almost 60 years as a bleaching agent in the pulp and paper industry and has more recently been used as an environmentally friendly way of purifying drinking water. It has even been used in some mouthwash and toothpaste products. In controlled experiments, the gas has been shown to kill bacterial spores, such as those of the anthrax microbe, by perforating the spore wall. However, the gas is potentially explosive and some have raised concerns about the safety of using it in such a large building.

A promising new products being developed in this category is that of one company, which has developed tiny metal particles–nanoparticles–that act like a gas, floating on the air and destroying chemical and biological agents on contact. These nanoparticles are currently undergoing testing by the DoD and the Department of Energy.

Liquids solutions and foams–Rooms and vehicles, and equipment that is not sensitive to chemical reactions can be decontaminated by washing with a liquid solution or foam. These can be applied directly to the contaminated surface and are more controllable than reactive gases. However, they may be impractical for use in an office environment because they can cause damage to paper files and computer systems.

Bleach and formaldehyde have been extensively used as biodecontaminants. A 10 percent solution of household bleach, is safe and effective in the lab and in wiping down counters or floors.

Page 14 PREV PAGE TOP OF DOC Segment 1 Of 2 Several new disinfectants are currently under development in this category, too. A new foaming agent has been developed by Sandia National Laboratory. Another new technology, called a nanoemulsion, has been developed at the University of Michigan with funding from the Defense Advanced Research Projects Agency (DARPA) in DoD.

As part of the DoD's response to the National Defense Authorization Act for FY 1997, the Department initiated a program to test the effectiveness of a number of decontaminants, many of them developed with DoD funding, that could be used in a civilian setting. In these tests, DoD evaluated the effectiveness of a variety of decontaminants in killing bacteria that had been applied to various materials found in an office environment, including acoustic ceiling tiles, carpet, latex painted wallboards, concrete slabs, painted metal, wood paneling and fabric-covered office partitions. The bacteria in the tests are a spore-forming bacteria related to anthrax known as Bacillus globigii.

So far, a number of promising options for decontamination have been tested. In these tests, the Sandia foam appears to neutralize or kill numerous chemical and biological agents such as soman gas, persistent nerve agent (VX), mustard gas, anthrax spores and viruses, while the nanoemulsion appears to be effective in killing a broad-spectrum of microbes.

Effectiveness of Decontamination

One significant question identified by the Department of Defense regarding decontaminating civilian sites is how to determine when, or if, a building that has been attacked with biological weapons is clean enough for people to return. In other settings, for example when sterilizing for commercial purposes in the food or pharmaceutical industries, a tremendous reduction in the number of bacteria is required-at least 99.9999 percent. (Sometimes this is called a six ''log'' or logarithmic reduction or a reduction by six ''nines.'') Army regulations for military decontamination scenarios, however, are less rigorous and require that bacteria be reduced by 99.5 percent at a minimum, or 200-fold. What level of reduction is necessary in civilian buildings-and what level of reduction would be demanded by the public-is still an unanswered question.

Complicating efforts to answer that question is the uncertainty over the degree of exposure to a biological agent that is necessary to cause disease. For some types of disease, such as Ebola, as few as one or two individual virus particles may be enough to cause the disease. For anthrax, the level of exposure appears uncertain. In the wake of the recent cases of anthrax, the public has heard from many government officials and medical consultants to the news media that the number of spores necessary to cause the inhalation form of anthrax is about 8,000 to 10,000 spores.

But the relevance of those number to humans appear questionable for a number of reasons. First, they were derived in the 1960s from experiments on rhesus monkeys, as experiments on humans raise obvious ethical concerns. Second, they represent the number of spores that caused disease in half of the population of exposed monkeys. The number of spores necessary to cause disease in, say, the most sensitive 10 percent of the population of monkeys is unknown and could be far lower. Finally, the recent cases in which postal workers contracted the disease from letters passing through the mail handling system has led some in the scientific community to question whether humans might be more sensitive than monkeys. How many spores are necessary to cause disease in humans-how many are medically significant-is unknown.

Conclusion

An important part of dealing with the threat of biological terrorism is developing the capability to decontaminate civilian facilities safely and effectively. In order to effectively decontaminate civilian office buildings and minimize the disruption and dislocation biological attacks cause, we must develop methods that can be used to decontaminate public buildings without destroying the kinds of sensitive equipment and building materials commonly found in civilian offices. We must also develop methods to determine, to the best extent possible, whether and when a contaminated building has been made safe enough for people to reenter and reuse.

Questions and issues to be discussed at the hearing:

1. What are the gaps in our knowledge of decontaminating infectious agents that hinder our nation's ability to respond to attacks by biological weapons, and what is the Federal government doing to fill those gaps?

2. What research is the Federal government currently conducting to identify methods and agents to decontaminate civilian office buildings, and what more research must be done?

3. How can the Federal government ensure the safety of people reentering and reusing a building previously contaminated with a biological agent? How can Federal agencies determine when, or if, a building contaminated with a biological agent is safe for reuse?

4. What kinds of research must conduct to improve our understanding of the threat posed by low levels of biological or chemical agents? Does the government have at its disposal a sufficient number of decontaminants approved for use in decontaminating facilities attacked with biological weapons?

Decontamination of Anthrax and Other Biological Agents

Chairman BOEHLERT. The hearing will come to order. We are here this morning to focus on one of the most essential, yet, one of the least discussed, aspects of the fight against bioterrorism: the decontamination of buildings. We have all had a kind of home-schooling crash course in decontamination in the recent weeks, trying to piece together a comprehensible picture from snippets of newspaper articles, and questionable official statements.

Today, instead, we get to have Decontamination 101, a thoughtful, comprehensive overview of what we know and what we still need to know from acknowledged experts in the field. We plan to follow up on our education by holding a hearing with the Federal agencies that are responsible in this area, if we can find them.

I say that half jokingly. The Federal efforts on decontamination, in terms both of emergency response and R&D, are fragmented enough to make Humpty Dumpty blush. Civilian and military agencies are involved, different portions of agencies are involved, classified and unclassified research is involved. The whole effort simply does not cohere. That has to change.

Some preliminary ad hoc efforts are being made to overcome all the balkanization of effort. Jack Marburger, the President's Science Advisor, has pulled together teams from agencies. For example, my staff was given an impressive briefing yesterday from the team dealing with mail decontamination. Agencies have been pulled together in the effort to figure out what to do about the Hart building.

But if the Hart building exercise is any indication, we still have a ways to go in developing an ongoing, coordinated way to soberly evaluate different decontamination strategies.

For starters, we need to be much clearer and direct about what we don't know. Among the key things we don't know is how clean a building needs to be to prevent disease. Many officials, including some officials of the House, continue to quote the figure of 8 to 10,000 spores to be infected with inhalation anthrax, even though CDC has moved away from that figure, which was based on a questionable interpretation of relatively old animal studies which may not applicable in this situation to start with. So we need to be careful. We need to be precise. We need to be direct with the American people. I might say that

Mayor Guiliani is a model in that regard.

So today, we will start this process of being more careful, with this very hearing, to ensure that Members of Congress know whereof they speak. Hopefully, others will follow suit.

The Federal Government needs a much better coordinated emergency response, R&D, and communications program related to decontamination. The effort to build that program begins with this hearing, and I look forward to the testimony from our expert witnesses. And I want to thank all of them for serving as resources to this Committee. We very much look forward to your testimony.

And with that, let me recognize the distinguished gentleman from Texas, the Ranking Member, Mr. Hall.

[The prepared statement of Mr. Boehlert follows:]

PREPARED STATEMENT OF CHAIRMAN SHERWOOD BOEHLERT

We are here this morning to focus on one of the most essential yet one of the least discussed aspects of the fight against bioterrorism-the decontamination of buildings. We have all had a kind of home-schooling crash course in decontamination in recent weeks-trying to piece together a comprehensible picture from snippets of newspaper articles and questionable official statements.

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The Federal Government needs a much better coordinated emergency response, R&D and communications program related to decontamination. The effort to build that program begins with this hearing. I look forward to the testimony.

Mr. HALL. Mr. Chairman, thank you. And I certainly agree with the statements you have made. And this very malicious thing-and these attacks in Florida and New York, Washington have pretty well left us not only paralyzed, but terrorized. And I thank these four members here who have given their time and have prepared themselves back through the years to bring this testimony to us and then give us their time today. I know your time is valuable and I thank you. And, Mr. Chairman, I want to be very brief because I have one other that may want to use a little of my time here. And I would yield it back to you.

But we have witnessed the devastation here. We have had five postal workers, two of them have died, a lot of Washingtonians, including a lot of people right here on Capitol Hill, are currently taking antibiotics.

I have even been affected adversely by it. When I flew in here last week, somebody picked me up and I said take me straight to the office. He said, well, I will take you there, but you can't get in. And then the thought suddenly occurred to me, well, I just need to get my car. And one of the major reasons I needed to get my car was that my keys to my apartment were in it. And I was a street person there for about eight hours. Finally found a way to get into my apartment and the window people are going to come back and put the glass back in when they come back.

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But it has been over three weeks now since this stuff was discovered in the Hart Building, and there is still not a consensus plan for it. And I expect, Mr. Chairman, this will be a series of hearings that we are going to have on this because we have a long way to go. And I would like to-is Mr. Baca here?

Mr. BACA. Yes.

Mr. HALL. And Mr. Baca, I think, has a short statement and I would like to yield some of my time that is left to him.

Chairman BOEHLERT. All right.

Mr. HALL. And I have-what did I have, 15 minutes?

[The prepared statement of Mr. Hall follows:]

PREPARED STATEMENT OF THE HONORABLE RALPH M. HALL

Mr. Chairman, I want to congratulate you for convening a hearing on this important subject. The malicious anthrax attacks of the past month in Florida, New York, and Washington have left the nation terrorized and made biowarfare a household word.

Here in Washington, we have witnessed firsthand the devastation a small amount of anthrax sent through the mail can have. Five postal workers contracted inhalation anthrax, the most deadly form of the disease, and two have died. Numerous Washingtonians, including many working on Capitol Hill, are currently taking antibiotics because they were or may have been exposed to anthrax. Spore contamination was found at several Post Offices and four Congressional Office Buildings. Though the Post Offices and most of the affected Congressional buildings have reopened, the Hart Senate Office Building and several House offices remain closed.

We are now scrambling to clean buildings contaminated with anthrax spores. Unfortunately, the book Decontamination for Dummies has not yet been published. Scientists, engineers, and government officials are working furiously to sift through information and studies on disinfectants and technologies powerful enough to destroy anthrax spores dispersed throughout a large, structurally complex building. It is now over three weeks since anthrax was discovered at the Hart Building and there is still not a consensus plan for decontamination of the building. Last week we heard that they were going to attack the spores with chlorine dioxide. Monday we heard that they were not going to use chlorine dioxide, and Tuesday we heard they were going to use chlorine dioxide in Senator Daschle's and Senator Feingold's offices and a disinfectant foam elsewhere. I wonder what today's plan is? Obviously, there is a not enough known about the logistics of large-scale biodecontamination of biowarfare agents.

I expect that this will be the first of a series of hearings in this committee investigating the science and technology of bioterrorism. In future meetings, I would hope that we will look at the decision-making process that Federal agencies use in formulating decontamination plans, as well as the adequacy of civilian and military R&D programs to address this urgent need.

Once again, I'd like to thank the Chairman for holding this hearing, and I am looking forward to hearing from our distinguished witnesses.

Chairman BOEHLERT. Mr. Baca is recognized to consume the--

 Mr. BACA. Short remainder of the time.

Chairman BOEHLERT [continuing]. The remainder of Mr. Hall's time.

Mr. BACA. Okay. Thank you very much, Mr. Chair. It is--as we have indicated, I guess this is too close to home to all of us. And many of us were affected by what happened. I personally was, along with many of the other individuals who are in the Longworth building. We felt what it was like to be homeless for a while because we basically did not have a place to go to. And the effects it had on our staff, too, as well to carry on the business as usual.

It became very difficult for many individuals here in D.C., and for my staff, as many others--the effects it had on them. And the effects of being worried, too, as well--wondering in terms of if we were able to decontaminate everything that came into our office. Did it come into our office? What offices were affected by it? There was a lot of doubt. There was also a lot of hesitancy too, as well, and we still wonder in terms of the mail that even comes in, into our office, too, as well.

And we are looking at the ventilation in the area. Was it, in fact, cleared? Is it cleared? The thoughts are still there. People are still worried about what is going on. We are still very frustrated with the--with what is going on, and hopefully that we will be able to take care of our frustrations and go on with taking care of what needs to be done.

We must also, you know, keep in mind that we must not let the terrorists stop us from performing our duties or our responsibilities. We must continue to do what is necessary and let the world know.

With that, I would like to say is that no one at Longworth feels really very safe. And we're hopeful that the danger is over and that the building is decontaminated--we need to know how effectively has this decontaminated the building to protect the civilians and also to get back to work. I think it is very important that we protect every individual who comes into any one of our

buildings, whether it is the Longworth, whether it is the Cannon, whether it is Rayburn, or the Capitol, or throughout the Nation, too, as well.

I think the subject today is so, so important to all of us to find out what can be done, and we look forward to hearing your testimonies. And I yield back the balance of my time.

[The prepared statement of Mr. Baca follows:]

PREPARED STATEMENT OF THE HONORABLE JOE BACA

This hearing today hits a little too close to home. My office is located in the Longworth Building. As everyone knows, the detection of trace anthrax forced the Longworth inhabitants out of the building for two weeks. For two weeks my staff and I struggled to go on with ''business as usual'' working out of temporary offices in Washington, DC and California, while we worried about ourselves and our friends in the building. We wondered were we exposed? We also felt the frustration of being forced out of our place of work. Surely this is what the terrorist had in mind--disrupting our government and disrupting the lives of hard-working Americans. We were eager to return to our office, to be able to answer our calls and e-mails, and to reassume my constituents that their congressional office was okay and WORKING. However, we had to make sure it was safe to return to the building. No one wanted to put the Longworth staff in danger. When a building is contaminated, we need to know how to most effectively decontaminate a building to protect civilians and get them back to work! I think everyone now know that bioterrorism isn't paranoia--it is a terrible part of our new reality and we need a plan.

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Mr. Chairman thank you for calling this hearing and I look forward to the testimony our witnesses have to say.

[The prepared statement of Representative Constance Morella follows:]

PREPARED STATEMENT OF REPRESENTATIVE CONSTANCE MORELLA

Mr. Chairman, once again science has taken center stage in our daily lives. Unfortunately, as we have recently seen, this is not always good. Bioterrorism has gripped the nation and we are quickly learning how unprepared we are for its arrival. I commend the Chairman on his leadership in calling attention to this critical issue.

Today, we will not be dealing with how to prevent bioterrorism, but what to do when an event occurs. Critical questions will need to be asked, and unfortunately, I do not believe that we will have many answers. We have neglected this issue far too long and the gaps in our knowledge are far too wide. Nevertheless, it will be up to us to determine an appropriate response.

Clearly, safety should be our primary goal. Unfortunately, the scientific community does not seem to know exactly what safe means with regard to these biological agents. Without this information, how do we assess the risk? Complicating matters further, we are also unsure of the risks associated with current decontamination protocols. Will they work? And if they do, will the cure be worse than the disease? I hope today's panelists will be able to give us some insights into these issues.

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Even without the technical problems, there are still some fundamental questions about what is an appropriate response. Some would argue for a precautionary approach; that in the face of uncertainty we should move forward with aggressive decontamination efforts. However, this raises other questions. What is the best decontamination approach? What is the cost? Are we going to decontaminate all buildings are only those at high risk? How would we determine

what that means?

On the other end, there are those that argue the risk is minimal and we should do nothing. They argue that secondary aerosolization is unlikely and that vaccines and antibiotic prophylaxis is a sufficient response. However, these seem to me to be small comfort to the people who actually work in the contaminated buildings.

There seems to be little middle ground between these positions but we need to find a way to assess the risk and formulate a sound policy. Without concrete answers to our myriad of questions, this will be extremely difficult. I hope our panelist will be able to provide some and I look forward to their testimony. Thank you.

[The prepared statement of Representative Jerry F. Costello follows:]

PREPARED STATEMENT OF THE HONORABLE JERRY F. COSTELLO

Good morning, I would like to thank all of the witnesses for appearing before our committee to discuss recent anthrax scares as well as potential threats from other biological agents. As you are well aware, this is a very important issue, and will continue to be so for a very long time.

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I think it is important for us to remember these are very real threats, however, we must also strike a balance between addressing these threats and ensuring we do not instill unnecessary fear in individuals. I am hopeful today's witnesses will enable us to more fully understand what goes into decontamination of affected areas and what new technologies are available to fight further infections of individuals and property.

Congress, and in particular this Committee, has shown great support for new decontamination technologies. I'm sure my colleagues will agree that it is in the best interest of everyone to support new initiatives that will provide the American people with a sense of safety. I am particularly interested in learning whether we have the right researchers and scientists to study and apply the new technologies, as well as learning what the cost implications will be.

I thank all the witnesses for being with us today and providing testimony to our Committee.

[The prepared statement of Representative J. Randy Forbes follows:]

PREPARED STATEMENT OF CONGRESSMAN J. RANDY FORBES

Thank you, Mr. Chairman and Ranking Member, Mr. Hall, for holding this hearing today. I also appreciate our witnesses taking time from their busy schedules to join us in this important discussion.

Page 28 PREV PAGE TOP OF DOC Segment 1 of 2 As we have been learning each day since the September 11th attacks, it is difficult, if not impossible, to get out in front of biological or chemical terrorism. There are countless agents that can be used and countless methods for releasing them. To complicate matters even more, many of these agents and methods are somewhat commonplace or can be accessed or manufactured. The knowledge is available and our enemies have limitless imagination.

Thus far, we have focused on how to detect these attacks and how to treat the victims. But, we must remember that our enemies are not only seeking to harm the American people, but also the American way of life. Even those attacks that may not cause many deaths or illnesses can bring our systems of commerce and daily routines to a screeching halt. We must be prepared to return our

infrastructure to their previous states, and quickly.

I am pleased to see that so much research has been ongoing in this area, and that America's scientists are well-positioned to address this issue now when we need them to most. I am hopeful that Congress and the Administration will be able to partner with these experts to expedite their research.

Thank you.

Chairman BOEHLERT. Thank you very much. And the first Panel--I will introduce two of the panelists, and I will recognize Representative Bartlett and then Representative Rivers for the purpose of introductions. At this point, I ask unanimous consent that all additional opening statements be placed in the record at this juncture.

Our first Panel, and our only Panel of the day, consists of Lynn Goldman, a Pediatrician and Epidemiologist. She is a Professor at the Johns Hopkins University Bloomberg School of Public Health, where her areas of focus are environmental health policy and children's environmental health. She co-chairs a school-wide response to terrorism threats. Her appointment is in the Department of Environmental Health Sciences with a joint appointment in the Department of Health Policy and Management.

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We have Dr. Charles Haas. He is an Environmental Engineer with significant experience in microbiology, disinfection, and risk assessment. He is a Professor at Drexel University in Philadelphia.

The Chair recognizes Dr. Bartlett.

Mr. BARTLETT. Thank you very much, Mr. Chairman. I welcome this opportunity really to make two introductions. The first is to introduce a truly unique facility, which is in the district I have the honor of representing. It started out as Camp Detrick. It is now Fort Detrick. And it is unique in this country, and, except for Russia, it is unique in the world. Because for, what, 40 years, this institution has worked with the kinds of agents that terrorists are now using. They have had to clean up their facilities and so they have had extensive experience with clean-up.

Fort Detrick has one of, what, just two or three Level 4 containment facilities in this country. There are very few others in the free world. Well, I guess Russia is now in the free world too. But Russia inherited an enormous cape of infrastructure in Level 3 and Level 4 containment facilities from the Soviet Union, where they didn't have just small buildings as we have at Fort Detrick. They have--they had enormous complexes that were at this level of containment.

Very few people know what a Level 4 containment facility is. Maybe Mr. Barbeito, which is my second introduction, will be able to explain it to us. But he has really extensive experience. I doubt that there is another person in America who has more experience with clean-up, because he was doing this after the experiments at Fort Detrick for many, many years before he went to the National Institutes of Health as Biological Safety Officer and then the United States Department of Agriculture. In 1996, he retired and now his country is calling him back into action because he is one of the real authorities in this country on clean-up, having had all of this experience. Mr. Barbeito, we are really delighted that you are here today, and thank you for representing our district.

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Chairman BOEHLERT. Thank you very much. Congresswoman Rivers.

Ms. RIVERS. Thank you, Mr. Chair. It is my pleasure today to introduce Dr. James R. Baker, Jr., who is the Ruth Dow Doan Professor of Biologic

Nanotechnology at the University of Michigan. He is-he got his undergraduate degree from Williams College in Williamstown, Massachusetts. He has a medical degree from Loyola-Stritch School of Medicine, and he completed his internship at the Walter Reed Medical Center in Washington.

He currently is on the faculty of the University of Michigan. He has worked in several areas-the Division of Allergy, the Division of Pathology, and he was the Director of the Histocompatibility Laboratory there, as well. In 1993, Dr. Baker was appointed as Chief of the Division of Allergy in the department.

His research has been in the area of auto-immune endocrine disease. He's been involved in developing gene transfer clinical protocols at the University of Michigan. This work led him to develop a new vector system for gene transfer using dendrimers.

This work with dendrimers, led Dr. Baker to establish the Center for Biologic Nanotechnology. This Center is leading a multidisciplinary project that works toward the development of new therapeutics for cancers based on dendrimers.

Another major interest of Dr. Baker's is, of course, the one we are going to hear about today. He focuses on preventing pathogens from entering the human body which is a major goal in the development of countermeasures to biological warfare.

I was so excited when I found out about this company, about Dr. Baker's work through the University, and the products that they are just about ready to market. I think everyone will be very interested in what they have to say. Thank you, Mr. Chair.

Chairman BOEHLERT. Thank you very much. And to our panelists, once again, thank you for serving as resources to the Committee. We will proceed from left to center, with Dr. Goldman, Dr. Baker, Dr. Haas, and, Mr. Barbeito. And we would ask that you try to summarize your statement. I am not going to be arbitrary, but try to keep it to five or so minutes, and then that will allow more opportunity for questions. With that, Dr. Goldman, welcome. Microphone, please.

STATEMENT OF LYNN R. GOLDMAN, MD, MPH, PROFESSOR OF ENVIRONMENTAL HEALTH SCIENCES, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, BALTIMORE, MARYLAND

Dr. GOLDMAN. Thank you very much. We are, I think, all pleased to have the opportunity to testify before you today. You have asked us a number of important questions, and, in my testimony today, which I will summarize in my oral testimony, I will address these questions. And, in addition, I am going to take a moment to share my thoughts about some of the broader science issues that need to be addressed.

The first question had to do with assuring that decontamination is successful. This is a very important question. The knowledge about decontamination for infectious agents has been developed in numerous areas like drinking water, food safety, medical facilities, and in industrial applications.

And within the government, the Environmental Protection Agency and the Food and Drug Administration both have responsibility for regulating disinfectant agents. However, the roles that these agencies play have to do with evaluating and deciding whether to give regulatory approval to products that are brought forward by the private sector for use commercially. And they have very little in the way of proactive research and development efforts in this area. And in places where there isn't a clear market niche, there is not going to be very much going on in a system like this.

And I would posit—I think that it is quite provable that there probably wasn't much of a market prior to this October for disinfectants for mail, for the mail handling system, for offices that receive and handle mail, or for people who are engaged with mail.

In short, there would have been no real incentive for the private sector to engage in research in this area, and given that there is no research going on within the government, here we are in a situation where nobody has really given this much thought.

Yet, the need for disinfection is immediate. In thinking about alternatives for disinfection, obviously, there needs to be a fundamental understanding about the nature of the organism, in this instance, that we are trying to kill, which is an anthrax spore. An anthrax spore is very resistant to most forms of disinfection. The reason for that is that they are, in essence, hibernating. They are not growing and metabolizing. And many of the substances, many of the methods that are used to kill organisms, take advantage of metabolic processes, block metabolic processes as a way of killing organisms. And we know that spores can persist for very long periods outdoors. There is no reason to assume that they wouldn't persist for long periods within buildings, as well.

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I am not going to go through, in my oral testimony, the list of what we know might be used as treatments. There is certainly heat, various forms of radiation, including ionizing radiation and UV radiation, various disinfectants, some of which have been used in the past for anthrax, others of which have been used in other situations and may be applicable to this use.

None of these have been developed or tested for the current situation, and a number of them have obvious shortcomings for dealing with buildings, complicated HVAC systems in buildings, and the mail.

So in any crisis, it is important to step back and consider how science can best inform the decision-making process. How should we be assessing the risks and benefits of multiple alternatives in this kind of a situation? And I would say that what we need is what I would call a safety assessment. A safety assessment looks at three important factors—the efficacy of the treatment options, the risks to health and the environment that are side effects from the treatment options, and also the feasibility, in terms of the time, the cost, and the destruction of property that might occur from various treatment options.

And the first issue, efficacy, is a given. Any option has to be absolutely efficacious when you have a potentially lethal organism. And this is a challenge because spores might be within papers, within HVAC systems—you know the story. And it might be difficult to reach the spores.

Second, there is an issue of risks to health and the environment. Some of these can be avoided by using care and caution, by using appropriate procedures. But, you know, some even low levels of risks might be tolerable if you are preventing a very serious disease.

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And an analogy I like to use is in the area of pharmacology. We tolerate much greater side effects from a medication that treats cancer than we would from a medication that treats a headache. And this is a serious disease and so we might be willing to tolerate a greater degree of potential risk.

And then there are issues of feasibility. And, as you all know, some of the options may require a lot of time, a lot of resources. Some might cause damage to computers and electronic equipment, to furniture, to valuable artwork. And so these tradeoffs need to be considered. And also, the urgency, in terms of vital government functions in reoccupying buildings and reusing facilities. These must

be considered in managing this issue.

The second question has to do with the major challenges that government agencies face. And I think that the most important challenge has been that the government needs to develop a very clear method of assessing the safety of buildings and protection of people, and of managing the risks. And so far we haven't seen the development of that kind of a framework.

We need a clear rationale for which buildings need to be assessed. We need statistically based sampling protocols for buildings. How many samples should we take? Where should we take them? How can we be sure that we are really characterizing the risks? This is critical. And we do know a lot about how small particles behave in buildings. We know a lot about indoor air pollution. We need to apply our knowledge, apply the models that have been developed, to have a science-based process for doing this.

Another critical need is a set of rapid and reliable laboratory assays. Now, many assays have been developed and many are under development, but we need to have those assays used within a framework that tells us that we have the needed sensitivity—that it is finding the anthrax, if it is there—and the needed specificity. We don't want to be crying wolf and having false positives that tell people 1 day there is anthrax, the next day, oh, no, it is not actually there. We need to have the specificity that says, if the test is positive, that anthrax is there.

The decontamination strategies should take into account the safety needs of the public and workers and buildings. You know, facilities will need to be aired out after treatment and employees will need to have adequate education about what they need to do to protect themselves. If there is food in the building, they may need to discard it. They may need to wash their dishes—people have cups and dishes around their office buildings. If women in the building are pregnant, or may be pregnant, or if they are nursing, that needs to be considered in terms of protection of the unborn or of their infants.

In the longer term, I would say there needs to be a function within the Federal Government that is responsible for the issue of public health pesticides, and probably that it needs to be at the CDC. Even before anthrax, we were facing the problem of West Nile virus that had arrived on our shore. And, you know, what were the appropriate treatments for West Nile? What should New York City be doing to eradicate mosquitoes in a highly urbanized area full of people? We have not had that public health function in the government. I think that bioterrorism simply underlines this problem and makes it into a much more urgent problem than it had been even before with the problem of emerging infections.

The next question has to do with research needs. And, certainly, there is a research need that has to do with developing protocols for sampling buildings. I have already talked about that. We need to have statistically-based methods of determining whether there are anthrax spores in the HVAC systems and other locations in buildings. We need to understand more about exposures to people in the postal system and others who handle mail. And that could be done by actually monitoring individuals.

 We could also learn more about contamination of the mail by running surrogates through the mail system to see what actually happens as a letter is moving through that has substances in it. And we need to develop methods for decontamination of buildings, both in the short term, but also, longer term. We need to be thinking about how do we better design work practices and how do we better design buildings to prevent hazards in those buildings in the first place?

And, last, but not least, is the issue of risk communication. How do we communicate these risks to the public in a way that gives them the straight facts, but does not sow terror and fear, because, after all, that is the object of the terrorists? And there—and this is a real opportunity to generate knowledge in this area that I think will be very important in terms of understanding how these crises should be managed in the future.

Some comments on public health science. Obviously, we need to continue to develop the vaccines and the therapeutic agents that will be important in protecting us against bioterrorism. But also critical is the need to strengthen our Nation's public health systems. What will be the next attack? It may be anthrax, but it may be chemicals, it may be other organisms, it may be something else. And we need to have a strong public health system that includes epidemiology and investigators at all levels, laboratory capacity, and data-tracking systems. And I think it is very clear that this system is in disarray.

This strengthening of our systems should include strengthening of the training and development of the public health work force, including the academic schools of public health.

Page 37 PREV PAGE TOP OF DOC Segment 1 Of 2 I want to thank you again for inviting me to come and talk to you about this very important and complex issue.

[The prepared statement of Dr. Goldman follows:]

PREPARED STATEMENT OF LYNN R. GOLDMAN

Chairman Boehlert, Congressman Hall and members of the Committee, thank you for the opportunity to come before you to provide perspective on our nation's ability to respond to this crisis of anthrax and bioterrorism.

My name is Dr. Lynn Goldman and I am a pediatrician and an environmental epidemiologist. I have an extensive background in the area of pesticide health and environmental effects and environmental risks to children. Between 1985 and 1992 I served in various positions in the California Department of Health Services, most recently as Chief of the Division of Environmental and Occupational Disease Control. Among other things, I was responsible for the conduct of a number of epidemiological investigations of the impacts of environmental exposures to health, especially the health of children. In 1993 I was appointed by President Clinton and confirmed by the Senate to serve as Assistant Administrator for Prevention, Pesticides and Toxic Substances at the US Environmental Protection Agency (EPA). In that position, I was responsible for the nation's pesticide and toxic chemicals regulatory programs at the EPA. In January 1999 I left the EPA and joined the Johns Hopkins University where I presently am Professor at the Bloomberg School of Public Health. At Hopkins, I am one of the co-chairs of our school wide task force that is responding to terrorism. Also, on a pro bono basis, I have provided consultation to the American Postal Worker's Union on issues related to anthrax in the postal work environment. I receive no support for doing work in this area at this time.

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In your letter of invitation, you have asked a number of important questions. In my testimony today, I will address three of these questions. First, what role does decontamination play in an overall government response to biological attacks? What must the government do in order to ensure that decontamination is successful? Second, what are the major challenges that government agencies face in decontaminating civilian facilities and is the government prepared to meet them? Third, what are the major research questions that must be answered to improve decontamination, and what agencies are or

should be currently pursuing those questions? In addition, I will share my thoughts about some of the broader science issues that need to be addressed.

Assuring that decontamination is successful

The knowledge about decontamination of infectious agents has been developed in numerous areas: drinking water; medical facilities and medical devices; laboratories; food safety; and animal care. The Environmental Protection Agency and the Food and Drug Administration share responsibility for their regulation. The lead agency is determined by the intended use of the product. I will not go into the details of this but suffice to say that the FDA's primary roles are in medical device sterilization and the EPA is concerned with drinking water and industrial uses. It is fair to say that those agencies review products that are brought to them for approval, and do not do much research and development into new alternatives for decontamination. In other words, there are not proactive efforts to identify new methods to do pathogen decontamination. (Such activities may occur in other government agencies, however.) Generally, the private sector will fulfill market needs. However, in the case of bioterrorism, research is needed in areas where there are no clear market needs.

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Anthrax and other potential weapons of bioterrorism can be used in facilities where, under normal circumstances, there is no market for products. Until last October, there was no market for decontamination of the mail, mail transport equipment, mail sorting equipment and facilities, or office buildings where contaminated mail was received. Yet, as the current situation demonstrates very well, the need for disinfection is immediate.

In thinking about alternatives for disinfection it is important to understand the nature of the organism. Anthrax form spores when their cells are exposed to oxygen. Anthrax spores are highly resistant to cold, heat, chemical disinfectants, and long dry periods. Very little is known about their persistence in buildings but in my judgment they are likely to persist for a long time. Anthrax spores resist to many treatments because they are, in essence, hibernating. Because they are not growing and dividing they are not affected (as spores) by many antimicrobials that interfere with metabolic processes.

How can we kill anthrax?

Heat: Anthrax spores on contaminated materials can be destroyed steam under pressure (autoclave) for one hour; dry heat above 159C; or boiling water for 30 minutes with disinfectants

Radiation: Ionizing radiation (including X-rays, UV light and electron beams) are known to destroy anthrax spores, if delivered at a high enough dose.

Disinfectants: A number of disinfectants have been used including: peracetic acid; formaldehyde; chloride solution; potassium permanganate; hydrogen peroxide; sodium hypochlorite; and iodine

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Antimicrobial agents utilized in biomedical research facilities: A number of such agents may be of use including: Chlorine as Cl or as sodium hypochlorite (water); and chlorine dioxide, iodophors, phenolic compounds, quaternary ammonium compounds, alcohols, glutaraldehyde, and paraformaldehyde (hard surface disinfecting and sterilizing)

Therefore, there are a number of agents that possibly could be used. However, none of these have been developed or tested for the current situation. Moreover, a number of them have obvious shortcomings and are not relevant to decontamination of buildings and the mail.

In any crisis, it is important to step back and consider how science can best inform the decision making process. How do we assess the risks and potential benefits of multiple alternatives in this kind of situation? First, this problem should be defined as one of safety assessment. By safety assessment I mean an assessment that considers three important factors: the efficacy of the agent or agents in destroying viable anthrax spores to which people might be exposed, the safety of the agent or agents to health and the environment, and the feasibility in terms of time, cost, and destruction of property.

The first issue–that of protection of people from viable spores–is not as easy to tackle as it might appear on the surface. The disinfectant needs to be able to deactivate anthrax spores; to do so it needs to reach spores in any locations where humans may be exposed. This is challenging since such spores may be in paper, in ventilation ductwork, and on various surfaces, some of which might be difficult to treat with chemicals. Efficacy should be a given.

Second, there is the issue of risks to health and the environment. Most of the alternatives that I listed are associated with potential health risks. For chemicals, there are considerations of avoiding spills during transport, assuring that no one can enter the facility during treatment, airing out the residues post treatment, and so forth. There are similar safety issues for radiation. Low levels of risk might be tolerable in a situation where a rapidly fatal disease can be prevented. Such tradeoffs need to be carefully considered since prompt antibiotic treatment can be effective.

Finally, there are issues of feasibility. Some possible alternatives require considerable time and effort. Others may cause damage to computers, furniture, artwork, and so forth. There could well be tradeoffs between time, expense, and damages versus the need to reoccupy buildings to continue vital government functions.

Major challenges that government agencies face in decontaminating civilian facilities

The federal government needs to develop a clear safety assessment and risk management plan for the protection of people in contaminated buildings. Such a plan needs to include a clear rationale for whether a building requires testing and statically based sampling protocols for buildings. Such sampling protocols are critical if we are to be certain that the results of sampling can be relied upon as a basis for the assessment of safety, before a building is decontaminated, and for the determination of clearance, post decontamination. We know a lot about the behavior of small particles and about indoor air pollution. This knowledge needs to be applied to the situation of anthrax in buildings (which is complicated by complex ventilation systems and human activities). Modeling techniques could be developed to guide such sampling efforts.

Another critical need for sampling is a set of rapid and reliable laboratory assays for anthrax and other pathogens that will be used by terrorists. Many such assays have been developed and are in use. However, I have yet to see a validation of whether these have the needed sensitivity (ability to find anthrax when it is there) and specificity (low rate of ''false positive'' results) to be used for final decisions.

Decontamination strategies will need to take into account the safety needs of the public and workers in buildings. In many cases there will be no appropriate facilities for storage, mixing and handling of decontamination materials on site or near to sites. Such facilities may need to be constructed. Care will need to be taken to assure that members of the public do not wander into decontamination areas (as has occurred with methyl bromide treatment of homes). After treatment, facilities will need to be thoroughly aired out and to assure that there will not be exposure to workers to return to their offices or

work places. It would be wise to provide educational briefings to employees to ensure that they understand the risks, if any and their responsibilities (e.g., regarding disposal of food items that may have been left in offices or washing dishes and cups before using them). Special care should be given for women who are pregnant (or may be pregnant) or breast-feeding. If there is the potential for residual exposure, I think it generally is prudent to double reentry times since many substances have not been tested for the developing fetus.

In the longer term, there should be a function within the federal government, perhaps in the Centers for Disease Control and Prevention, concerned with the development of public health pesticides. Prior to anthrax, we were concerned with the arrival of West Nile Virus on our shore and the difficulties in treating mosquitoes, in highly populated and sensitive areas along the northeastern seaboard. Similar difficulties have occurred with prevention of hanta virus and other emerging diseases. Now we must be concerned about bioterrorism as well. This is an area where our public health system needs to be strengthened, in this time of emerging infectious diseases and emerging threats of bioterrorism. The infrastructure for public health disinfectants and pesticides needs to be in place before the next disaster.

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Major research questions that must be answered to improve decontamination

There are a number of areas of research that are important. Certainly, it is difficult to protect people against biological agents when you have so little information about how they move in buildings, and in the general environment. Here are a few of the areas that I think are important in the short term:

A protocol for sampling buildings: Develop statistically based approaches to sampling HVAC systems and locations within buildings

Exposures of postal workers and mail handlers: Use personal monitoring to assess the levels of respirable dust in the immediate vicinity of people who work with large volumes of mail. This could have immediate implications for intervening to protect people.

Contamination in the mail: Use surrogate organisms to assess how anthrax spores are released from the mail, in mail handling and processing. This would help understand spore concentrations and spread in the air, on surfaces, on mail, and on the clothing of mail workers.

Development of methods for decontamination buildings: Along with the development of decontamination methods, it should be considered whether there are modifications of building design and work practices, as well as means to more quickly identify hazards, that can be put in place to prevent or minimize contamination of buildings.

Risk communication: How do we communicate the straight facts to the public, without sowing terror and fear (which is, of course the real object of terrorists)? How do we talk to children about these issues? This time is an opportunity to generate knowledge in this area that will be essential to improving how these crises are handled in the future.

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Public health science

Efforts that already are underway in the area of development of vaccines and therapeutics against potential agents of bioterrorism are very important. In this regards, it is important to assure that children will be considered. As the mother of a five year old daughter, I worry that, should the need to arise to vaccinate for anthrax, that there is no FDA approved vaccine or dosage regimen for children. It is critical that such efforts use the same safety framework that I discussed above. That is, vaccinations and antibiotics need to be

The Decontamination of Anthrax and Other Biological Agents.txt delivered in a manner that assures that we ''first do no harm.'' One way to do this will be to improve our ability to diagnose exposure, and early illness, in people. In the short term, since we lack such tools, we need research on the acquisition of resistance to antibiotics by anthrax and other pathogens, as a consequence of the widespread use of antibiotics for prophylaxis.

Most critical is the need to strengthen our nation's public health systems. What will be the next attack? Will it be anthrax, another organism, or chemicals? Our public health system, which includes epidemiology investigators at the federal, state and local level, laboratory capacity, and data tracking systems, is in disarray. In 1988, the Institute of Medicine called for a fundamental overhaul. The nation has ignored this call and today we are living with the consequences. We need to strengthen our system for delivery of public health, as well as the training and development of the public health workforce. We need to strengthen our academic schools of public health so that they can provide the research, and the highly trained workforce, so that we can successfully defend ourselves from the threat of bioterrorism.

This is a large and complex issue. I appreciate your interest. Thank you again for the opportunity to testify today.

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Chairman BOEHLERT. Thank you very much. Dr. Baker.

STATEMENT OF DR. JAMES R. BAKER, JR., MD, RUTH DOW DOAN PROFESSOR AND DIRECTOR OF THE CENTER FOR BIOLOGIC NANOTECHNOLOGY; CHIEF, DIVISION OF ALLERGY AND IMMUNOLOGY; CO-DIRECTOR, CENTER FOR BIOMEDICAL ENGINEERING, THE UNIVERSITY OF MICHIGAN, ANN ARBOR, MICHIGAN

Dr. BAKER. Thank you, Mr. Chairman. I think I have a unique perspective here because we have been fortunate enough to be supported by DARPA since 1997 to investigate this problem and develop new solutions to biological decontamination.

And I think the first issue is, what is biological decontamination? And it is simply defined as removing organisms that are potentially infectious or dangerous from the building. But it is a much more complex issue. One has to look at both the type of organism, which determines the residual risk, and the chronicity of exposure. And these are things that have not been done in most of the studies that are already performed.

So the bottom line is, we need to develop an understanding for what we need to do in decontamination and what would be a medically acceptable residual level of contamination. And that is most important, because the real issue is here, can we put people back into these buildings safely? And that may be a much more complex issue than whether or not we can clean them up.

The problem at hand right now, as faced by the Hart building and several of the other buildings that we now have contaminated, is: can we actually reduce the contamination in those buildings to a safe level? Part of the problem clearly is that we don't know what a safe level is for residual anthrax contamination. And the studies that we do have aren't particularly enlightening in that. You mentioned the one study in primates where they gave immediate exposure to the animals and determined 8,000 to 40,000 spores. That was a single dose nebulization. It didn't look at chronicity of exposure and it didn't look at low-level exposure that might lead to other types of issues.

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In addition, as my colleague suggested, people are not all the same. And people with immune problems, people who are pregnant, people that have underlying respiratory conditions, may be more prone to infection with this. So setting a standard may be more difficult than we think, but certainly needs to be done.

I think there are four caveats, looking at moving into these buildings, that need to be addressed. The first is, the application of new technologies. There have been many new technologies proffered to do this. My start-up company has one that actually was approached to be used. Some of these technologies actually kill spores, which is reassuring. But, quite honestly, none of them have been tested appropriately, and, although they can remove spores from surfaces, the concept of trying to sterilize a building is something entirely different.

And I think what we need to really define is the fact that we will not be able to sterilize these buildings. We will not remove every spore. And we need to define for ourselves what is an acceptable or safe level to reduce contamination to, and how we will determine that. And I think that is really the key issue as we move forward.

Given the design of these buildings, we probably can't make blanket recommendations either. I think we are going to have to work to try and develop general approaches to how to address contamination: that different buildings may require very different technologies. And, in fact, the concept of trying to seal a building to decontaminate it, although very interesting, is something we haven't previously accomplished.

Finally, I think, the most important point here is to remember that these are truly experiments. What is being conducted on the Hart building is an experiment that we need to learn from. And, as such, we need to obtain appropriate data from the process to understand what has happened there and understand what is going to happen there.

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And that is where I would like to end. I think that the most important part of this process is not the decontamination of the building itself, but providing support for the individuals that have to reoccupy. Number one, these individuals must be given complete medical and psychiatric support so they feel comfortable returning to that building, whatever the contamination level is. And, number two, we need to follow these people prospectively so we don't get into a situation-if there are problems-where we don't know what has happened there, where we are looking and trying to figure out something from reports without having objective data on the individuals.

I think one other thing that might be helpful in this process is developing some type of commission, either within the government or without the government, to review this data and provide protocols and advice on how to proceed. And I see this working something like the Challenger Commission, where you would get scientists and physicians who are independent and able to review this and provide real-time feedback to the individuals who are in those buildings that will provide them both comfort and expertise.

So, in sum, sir, I think this is an issue that we need to address now. These buildings need to be cleaned and reoccupied, but we also need to do it in a manner that is safe and effective for both the people who will occupy them and for the surrounding neighborhoods that these buildings are located in. Thank you.

[The prepared statement of Dr. Baker follows:]

PREPARED STATEMENT OF DR. JAMES R. BAKER, JR.

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I am Dr. James Baker, a physician who is the Ruth Dow Doan Professor of Internal Medicine and Director of the Center for Biologic Nanotechnology at the University of Michigan. I am also the head of Allergy and Immunology in the Medical School. I am a 14-year veteran of service in the U.S. Military, 12 of it on active duty, including service during Desert Storm. With support from the

Defense Advance Research Projects Agency, the National Institutes of Health and NASA, my center is applying these technologies to a number of problems in biology including infectious disease therapy and microbial decontamination. I am also the CSO of a startup company, NanoBio Corporation, which is dedicated to commercializing new technologies for antimicrobial applications and decontamination. I have extensively studied the problems involved in preventing illness as a result of bioterrorism or bio-warfare, and I am pleased to have been invited to testify before the committee this morning.

The Issue of Biological Decontamination

It is first important to define biological decontamination. Decontamination might be simply defined as removing an agent from an environment or location. This process can involve many approaches, from the actual destruction of a location to something as minimal as simple washing. However, whatever the approach, it should remove the contamination without spreading the problem. The degree to which decontamination must effectively remove a contaminating organism depends to a great degree upon the agent. This relates to what I will call the concept of a medically acceptable level of residual contamination or simply the minimal number of organisms necessary to cause disease. This can vary greatly between bio-agents. For example, even one or two virions of Ebola virus can yield a productive infection if inhaled while several hundred anthrax spores may be necessary even for cutaneous infection. This also involves the persistence of stability of an agent in an environment. Unfortunately, the level of contamination that is tolerable with many diseases is not absolutely known. This is because most studies have only examined acute exposure and the effects of chronic, low-level exposure to pathogens or chemical agents are not well defined. Finite levels of residual anthrax spores that will be medically safe are currently not defined and open to debate. These must also be adjusted for individuals with defective immune defenses. Because of these issues, a rather simplistic concept of decontamination can become very complicated. Other factors that may confound our understanding of decontamination include the presence of more than one infectious agent in a contaminated site, which can lead to differing requirements, in part because exposure to more than one pathogen may increase susceptibility.

The Problem at Hand: Can We Decontaminate and Make a Building Safe?

The current problem is whether buildings that have varying levels of contamination with anthrax spores can be safely decontaminated. This is not a new problem. There are buildings at USAMRIID and West Desert Test Station at Dugway, UT that have not been torn down because of fears about anthrax spore contamination. Despite this, these buildings have been used without evidence of illness in the occupants. The concern is that the destruction of these buildings would spread spore contamination, and no effective approach to decontamination has been defined. We have, up until now, avoided decontaminating buildings for spores.

We are now acutely facing this problem. Clearly, we will have to remove anthrax from contaminated buildings given the number and importance of the sites that now exist. The primary goal will be to make these buildings safe for occupants and visitors, and the level of medically acceptable residual spore concentration must be first designated then achieved. Given this necessity, however, several caveats must be made.

1. New technologies will make it more likely that we can render buildings medically safe to reoccupy. A range of technologies from new oxidants and spore disrupting agents to vacuums has been under evaluation by the government and most can effectively reduce spore contamination on surfaces. Several of these agents can reduce spore counts on surfaces as effectively as bleach and paraformaldehyde with less toxicity. However, only a few technologies have been proven to kill spores. These share either a liquid or gas state and require

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direct contact with the spores. All oxidizing agents work in the same manner, regardless of format and have similar efficacy if used correctly and problems with toxicity. Newer approaches may allow decontamination without harm to the environment, sensitive equipment or valuable items. Using several of these techniques in combination should help reduce spore contamination on surfaces in contaminated buildings.

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2. Despite these technological advances, no building can be sterilized or treated in a way that removes every single spore. Total spore removal is achievable on surfaces, but cannot be done completely in a building given the complexities of the space. Therefore, techniques must be put in place to monitor residual levels of contamination and assure that a medically safe level of residual contamination be maintained.

3. Given the differences in the design of the buildings, each one will require an individual approach. For example, it may not be feasible to use the decontamination techniques that would work for smaller, more contained spaces in a building as large as the Brentwood Post Office. Safety for the environment and surrounding communities must be a priority in this process. However, as experience with the different decontamination approaches increases, it may be feasible to do things that we did not feel were possible a few months ago. We should remember that the UK was able to decontaminate an anthrax-contaminated island.

4. It is very important to remember that these decontamination protocols and processes are truly experiments. Nothing akin to this scale of building decontamination has been tried before, and it is not clear how effective this approach may be. Therefore, it is extremely important to conduct this work as an experiment, with appropriate data analysis. Only with this approach can we learn from this process and improve decontamination techniques for the future.

The Process of Safe Reoccupation of a Contaminated Building

As part of this experimental approach, I believe it is important to do two things after decontamination. The first is to provide support to those individuals who will be occupying the building after it is decontaminated. This support should involve both medical and psychiatric care so that each individual feels entirely comfortable reentering and reoccupying the space. Individuals displaced by a bioterrorism attack are traumatized to begin with, and will need additional help with reoccupation. Support groups may be very important in this process. Physicians should be readily available for any perceived problem that an individual may have after moving back in to a decontaminated building. In addition, the experiences of individuals should be recorded prospectively so that a better understanding of reoccupation is obtained. This may help to predict and prevent illness and the more data obtained from these individuals the better prepared we will be to handle these problems in the future.

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In addition, it may be particularly valuable to set up a review board of scientists and physicians to evaluate the outcome of decontamination and its effect on individuals who are reoccupying these building. This panel could function like the review board of the Challenger accident, but work on a more rapid manner given the immediacy of electronic communication. This is especially important since it is becoming clear that we don't fully understand the exposure tolerances for individuals to anthrax spores.

My hope is that these recommendations will help in the approach to decontamination of these buildings and will yield a better result for all involved.

Chairman BOEHLERT. Thank you very much. Dr. Haas.

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STATEMENT OF DR. CHARLES N. HAAS, L.D. BETZ PROFESSOR OF ENVIRONMENTAL ENGINEERING, SCHOOL OF ENVIRONMENTAL SCIENCE, ENGINEERING AND POLICY, DREXEL UNIVERSITY, PHILADELPHIA, PENNSYLVANIA

Dr. HAAS. I will start out talking about chlorine dioxide and then I will generalize it. And I find myself pleasantly echoing some of the remarks that have just been made.

First of all, just a wee bit of chemistry. Chlorine dioxide is not swimming pool chlorine. It is actually more oxidized material. In some sense, more reactive; in some sense, less reactive, but it is not the material that you put in your swimming pool.

Page 52 PREV PAGE TOP OF DOC Segment 1 Of 2 Chlorine dioxide has a long history of use in the drinking water field as a disinfectant. It has been actively used for about 50 or 60 years in this country for disinfecting drinking water. When it is used in drinking water, the gas is generated on a continuous basis and dissolved in water prior to application. It is known that dissolved chlorine dioxide is very active against viruses, vegetative bacteria, and protozoa. When I use the term vegetative bacteria, I mean bacteria that are actively growing. A bacterial spore is not vegetative and it is a dormant state.

The way in which chlorine dioxide kills microorganisms is very well understood. However, little attention has been devoted to inactivation of bacterial spores. Of course, in drinking water, frankly, spores have not been considered something that we need to protect against. But it is clear that spores are amongst the most resistant organisms to chlorine dioxide and to other disinfectants that might be used in water treatment.

The use of gaseous chlorine directly as a disinfectant is a development that occurred over the past 20 years. There have been several patents that were issued in the '80's and in 1990, and studies shortly thereafter occurred relating to the use of the gas to disinfect food processing equipment, medical equipment, and produce. However, there were apparently no refereed scientific articles pertaining to the use of the gas as a disinfectant for buildings or for the specific efficacy against spores of Bacillus anthracis.

A basic task in developing a decontamination strategy is the setting of a target clean-up level. I suspect many on this Committee have heard the expression, ''how clean is clean?'' It is a relevant expression in this context as well. The residual acceptable risk level after a clean-up, whether in this context or in, I guess, what I ironically call the more mundane context of superfund, is something that must be said after incorporation of use of stakeholders. This task requires the inevitable recognition that absolute certainty of absolute building clean-up is impracticable.

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Once this is defined-once the risk level that is desire to be achieved is defined, then the technical specifications for the amount of reduction that needs to occur can be set if the initial contamination and the pathogen dose response characteristics are known.

There are major engineering issues involved here. These factors, rather than the intrinsic inactivation rates, may set the time required for decontamination using a gas, such as chlorine dioxide. In addition, a gas, such as chlorine dioxide, is reactive. It will decay during application. And in order to get inactivation, the dose has to be kept up to an adequate level. And so it is important to understand that decay in order to understand how much dose of chemical you need to pump in.

The validation that the desired degree of reduction is achieved must be

The Decontamination of Anthrax and Other Biological Agents.txt performed using an indicator system. Whatever system is used must have documented performance with respect to the pathogens of interest, and sufficient samples must be taken to demonstrate reliable inactivation throughout the space treated. The removal of residual disinfecting gas from the buildings is essential and may also be time-consuming.

I have been asked to comment on the knowledge bases involved in understanding the problem, and I will simply mention four. There are certainly others. Analytical microbiology, the ability to measure the organisms in their state in which they occur. Chemical analysis of the disinfectants and of the byproducts that may result. The modeling of air movement and movement of contaminants through the indoor environment. And, finally, the health effects from inhaled chemical byproducts.

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Clearly, the expertise in the Federal Government lies over a number of agencies, and, as the Chairman said, I think some degree of coordination may be in order. I have outlined the list of research questions in my written remarks. These research questions are also multidisciplinary and will need to involve multiple Federal agencies and multiple disciplines outside the Federal Government.

I would like to leave you with a quote that appeared in an article published in 1999 by a group organized out at Johns Hopkins dealing with biological consequences of anthrax. ''Decontamination of''—this is a quote. ''Decontamination of large urban areas or even a building following an exposure to an anthrax aerosol, would be extremely difficult and is not indicated.'' 1999. Clearly, the recent events have changed attitudes and a resulting focused effort to address the scientific and practical problems posed by this challenge is required. Thank you.

[The prepared statement of Dr. Haas follows:]

PREPARED STATEMENT OF CHARLES N. HAAS

Mr. Chairman, Honorable Members of the Committee. I am Charles N. Haas, L.D. Betz Professor of Environmental Engineering at Drexel University. I have over 25 years of experience in the field of disinfection processes, and have also worked in the area of microbial risk assessment. I have chaired the disinfection committees of both the American Water Works Association, and the Water Environment Federation. I am a Fellow of the American Academy of Microbiology, and a Councilor of the Society of Risk Analysis. The opinions I offer will be those of my own and not necessarily those of any of the organizations with which I am associated.

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I would like to preface my remarks with a quote from a consensus paper on ''Anthrax as a Biological Weapon'', published in May of 1999 (25):

''. . .decontamination of large urban areas or even a building following an exposure to an anthrax aerosol would be extremely difficult and is not indicated. Although the risk of disease caused by secondary aerosolization would be extremely low, it would be difficult to offer absolute assurance that there was not risk whatsoever. Postexposure vaccination, if vaccine were available, might be a possible intervention that could further lower the risk of anthrax infection in this setting.''

The task of decontamination under the setting motivating this hearing is thus a very hard problem, that even recently was one not given high consideration.

Introduction

Chlorine dioxide was first produced from the reaction of potassium chlorate and hydrochloric acid by Davy in 1811 (31). However, not until the industrial scale preparation of sodium chlorite, from which chlorine dioxide may more readily be generated, did its widespread use occur (38).

Chlorine dioxide has been used widely as a bleaching agent in pulp and paper manufacture (38). Despite early investigations on the use of chlorine dioxide as an oxidant and disinfectant (2), its ascendancy in both water and wastewater treatment has been slow. As recently as 1971 (32), it was stated that ''. . .ClO2 has never been used extensively for water disinfection.''

By 1977, 84 potable water treatment plants in the United States were identified as using chlorine dioxide treatment, although only one of these relied upon it as a primary disinfectant (31). In Europe, chlorine dioxide was being used as either an oxidant or disinfectant in almost 500 potable water treatment plants (31). By the early 1990's in the U.S., between 500 and 900 water utilities were estimated as using chlorine dioxide either on a continuous or occasional basis (14).

The physiological mode of inactivation of bacteria by chlorine dioxide has been attributed to a disruption of protein synthesis (4). In the case of viruses, chlorine dioxide preferentially inactivates the outer protein layers, rather than nucleic acids (34, 35).

In applications in drinking water, chlorine dioxide is generated on an as needed basis by a controlled chemical reaction. Routes to generation of the chemical are generally either the reaction of acid with sodium chlorite or the reaction of chlorine with sodium chlorite. The generated gas has varying degrees of purity depending upon the generating system and its operation (16). In understanding the efficacy and potential side effects of treatment with chlorine dioxide, it is important to know how the gas is generated, and at what purity.

Once the chlorine dioxide is generated as a gas, it is dissolved into the water to be treated. The gas flow rate is controlled to maintain a desired dose of chemical agent. It has generally been found that chlorine dioxide provides superior inactivation with respect to a diverse number of microorganisms as compared to the more commonly used chlorine (1, 28, 29).

 The efficacy of chlorine dioxide as a water disinfectant is sufficiently well characterized that EPA has developed a set of tables predicting the degree of inactivation of microorganisms as a function of the concentration of disinfectant, the time of contact, temperature, and acidity of the water to be treated (30).

In the disinfection of drinking water, the target organisms of concern are disease causing viruses, vegetative bacteria (those that are actively metabolizing), and more recently pathogenic protozoa, such as Giardia and Cryptosporidium. In particular, bacterial spores (such as Bacillus) have not been the target organisms, because they have not generally been regarded as important waterborne pathogens. Very recently, investigators have started to assess the removal of spores through water treatment processes, including via disinfection, since their resistance more closely approximates the most resistant protozoa of concern (3, 6, 10, 13, 40).

State of Knowledge of Chlorine Dioxide Gas

The use of chlorine dioxide as a disinfectant/sanitizer applied directly as a gas is a development that has occurred over the past 20 years. Its use as a disinfectant for surfaces and implements (such as medical devices) was envisioned in a series of patents granted in the 1980's and 1990 (26, 42, 43).

In the medical sterilization field, the efficacy of a gaseous chlorine dioxide process was examined using as a test organism spores of Bacillus subtilis var niger (27). Performance was a function of temperature and humidity. At a relative humidity of 80% and a temperature of 30C, the time required for one log inactivation(see footnote 1) was 4.4 minutes at a gas phase concentration of 30 mg/L.

There has been recent work on the use of gaseous chlorine dioxide for applications in food processing. A group at Purdue University (22, 23) has reported on the application to disinfection of tanks used in the processing of fruit juices, and for microbial removal on produce. Their work also shows that inactivation is a function of temperature and humidity (as well as concentration of gas and exposure time). Although they studied a diversity of pathogens, none of the agents that they studied were spore-forming bacteria (or identified biological threat agents).

There does not appear to be any information published in the refereed scientific literature concerning either the use of gaseous chlorine dioxide as a decontaminating agent for large buildings or spaces, or on the sensitivity of biological threat agents (including Bacillus anthracis) to either gas phase or liquid phase chlorine dioxide. While it is plausible to believe that the sensitivity of B. anthracis spores towards disinfection is similar to the sensitivity of spores of other species of Bacillus (based on biological similarity), the lack of direct published evidence on this point represents a data gap.

Pros and Cons of Using Chlorine Dioxide Gas

Based on experience in the water industry, and those of other users of chlorine dioxide, the technology for the production of gas is a mature one and is available through several vendors. The analytical methods for measurement of chlorine dioxide, although requiring careful consideration, are well developed and understood. The mode of action on viruses and (vegetative) bacteria are well known.

 Several other gaseous materials are in common use that could be considered in the present context. These include chlorine and ozone. While chlorine and ozone both share the characteristics of wide experience of use, known and understood analysis methods, and modes of action, they have several important disadvantages with respect to chlorine dioxide. As noted above, chlorine is less efficacious (at least in solution) compared to chlorine dioxide. Comparative studies have shown that chlorine forms more byproducts from reaction with various organic compounds than do either ozone or chlorine dioxide (41). Ozone is substantially less stable (in both air and water) than chlorine or chlorine dioxide, hence it would be more difficult to maintain a concentration over a prolonged period of time than chlorine or chlorine dioxide.

There is limited information with all of these agents with respect to the target organisms under consideration, including bacterial spores.

Factors and Challenges to be Considered in Determining a Decontamination Strategy

A basic task in developing a decontamination strategy is the setting of a target cleanup level. This task-defining ''how clean is clean''-is conceptually no different than faced in other aspects of environmental remediation. For the particular aspects of biological warfare agents (as well as chemical agents), a framework for this decision can be set up using risk based principles. Like other applications, the residual acceptable risk level must be set after

incorporation of the views of stakeholders (37). This task requires the inevitable recognition that absolute certainty of absolute building cleanup is impracticable.

From an acceptable risk level, a value for the amount of residual biological agent (e.g., anthrax spores) that would be tolerable can be developed providing that information on the agent dose-response as well as exposure factors (e.g., breathing rates) are available. For most of the agents considered it might be necessary to rely upon animal data to assess target levels. Principles of quantitative microbial risk assessment have been developed, including by myself and colleagues (19). For some organisms it has already been shown that animal data provide good estimates of human risk (20, 21). There is animal dose response data for Bacillus anthracis that could be used to form the basis for development of target levels (5, 11, 15).

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Once a target level of microorganisms is stipulated, then given an estimate of the initial level of contamination, the ratio of these two numbers defines the degree of removal or inactivation that a decontamination system must achieve. As an example, if a particular room is estimated to have been contaminated by 100,000 spores, and if a final target level of 10 spores is deemed allowable (i.e., produces a sufficiently low risk), the a reduction of 99.99%, or 4 logs, must be achieved.

Given the degree of reduction that must be achieved, the required chemical concentrations and times need to be estimated from information on the rates of inactivation. This requires experimentation (likely using small-scale facilities) with the target organism(s) or suitable simulant(s). The objective of these studies would be to determine combinations of concentrations and times that result in the required degree of inactivation. This needs to be assessed as a function of temperature, humidity, and other factors that might influence the performance of the process. There is a large knowledge base on estimating kinetic parameters of disinfection processes (primarily in water and food applications) that is readily transferable to the problem of building decontamination (17, 18, 36). The results of these studies would have general significance, and once basic inactivation information was obtained, would not need to be repeated for each particular required decontamination event.

The results of these experiments would allow determination of the concentration of decontaminant that must be attained at every point at which microbial inactivation is needed. This concentration must be maintained for the required time to give the desired degree of inactivation. One of the important questions in implementation would be how much of a particular chemical (e.g., chlorine dioxide) needs to be fed into a building to achieve kill. This requires an understanding of the extents and rates at which the agent will transport through the entire space required to be treated, and the extent and rate of any decomposition reactions that will result in loss of chemical (and will thereby require additional material to be added).

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Chlorine dioxide gas has a rate of spontaneous decay. This is influenced by temperature, and likely relative humidity and light intensity. Superimposed upon these processes would be reactions with building materials. There do not appear to have been any direct studies of the reaction rates of chlorine dioxide with building materials or contents. However, it has been found that ozone gas (which as noted above is generally more reactive than chlorine dioxide) can react with interior latex paint or with indoor carpet (33, 39).

To assure that adequate levels of chlorine dioxide reach all locations in a space to be decontaminated, it is necessary to provide sufficient time and doses to achieve penetration of the chemical and to compensate for demand. No real time direct sensors are available to allow this penetration to be directly monitored, therefore some level of prediction of behavior would be necessary.

The prediction of distribution of chemical or physical components within a building is currently a forefront issue of research (8, 12, 24). Improving computer resources are allowing investigators to simulate the transport processes within buildings. However little investigation on transport of reactive materials within the indoor environment has occurred. Furthermore, the analysis of such transport characteristics requires site specific model development. Ultimately it may be possible to develop empirical safety factors for the level of dosing based on building size and configuration, however a substantial experimental and modeling effort would be required to develop these relationships.

A particular area of concern is the decontamination of sub-spaces within a facility that are relatively enclosed. Consider the potential to decontaminate a piece of mail in a desk drawer within an office by pumping chlorine dioxide (or any other gas) into the building or office. For decontamination to occur, the gas would need to diffuse into the desk (possibly through very narrow openings) and into the letter (through creases or cracks in the paper. The latter processes could in fact be quite slow and limit the efficiency of any gas decontamination process. Therefore, it is necessary to carefully specify the goals and limitations of decontamination with respect to such enclosed areas.

In implementing decontamination with chlorine dioxide, there are a number of aspects that need close attention. Perhaps the most important is devising a strategy to verify that the desired degree of reduction has been achieved in all locations where it is desired to achieve these reductions. The use of non-pathogenic indicator organisms, such as Bacillus subtilis (in the case where B. anthracis is the target organism of concern) is a reasonable approach. However experimental comparison of the relative sensitivity of the indicator and target organisms is required, and can be conducted in controlled and secure laboratory facilities.

Of key importance is that the monitoring for performance be made at a large enough number of locations throughout the facility to be decontaminated, and with enough samples collected, to provide strong assurance that the target level of performance has been achieved or exceeded. If only a small number of test organisms are examined for viability, it is easy to demonstrate inactivation, however the meaningfulness of the result is substantially less than if a larger number of organisms placed at a larger number of locations were assayed. The locations for placement of the test organisms should be representative of the sites within a facility at which decontamination is sought. If it is desired, for example, to decontaminate materials contained within desks or file cabinets then test organisms should be placed within such areas for post-treatment sampling.

The particular experimental method used to assess microbial viability after inactivation is a particularly important detail. These methods must be sensitive enough to measure the low levels of surviving cells that may be present, and they must be specific to differentiate between live and dead organisms. In general, methods that culture the organisms, for example on petri plates (for bacteria) or in cell culture (for viruses) are preferable, although these are slow (days to weeks). Molecular methods (relying on sensing DNA or biochemical components of organisms) frequently do not have the specificity to differentiate between live and dead organisms, however these are much more rapid.

There are additional issues that should be considered in the implementation of decontamination strategies using chlorine dioxide. During the period of treatment, concentrations of chlorine dioxide will likely exceed short term exposure limits for human toxicity (14), and therefore should personnel be required to enter the facility, appropriate personal protective measures would be required. The method of removal of chlorine dioxide after the required period of contact needs to be estimated, and the time required may be substantial.

Monitoring of air quality (for residual gas levels) should be conducted to verify return to safe levels prior to re-occupancy. The removed gas needs to be destructed(see footnote 2) to prevent external air pollution problems.

Although less reactive than ozone and chlorine, chlorine dioxide has the potential to react with organic material. In drinking water applications, organic products from the reaction with chlorine dioxide have been identified (41). There have been reports of reaction of chlorine dioxide evolved into the gas phase from drinking water with compounds released from new carpeting (9). It should be emphasized that the benefits from building decontamination likely would far outweigh any potential impacts from these resulting byproducts, however if widespread use of chlorine dioxide decontamination technology is foreseen, a program to assess potential reactivity and byproduct formation with indoor materials is justified.

There do not appear to been any systematic studies of the potential for gas phase chlorine dioxide to damage materials found in buildings. It is known, however, that in the construction of disinfection systems certain materials, including natural rubber, polycarbonate plastic and carbon steel should be avoided (14). Whether chlorine dioxide gas at concentrations that would be efficacious for building decontamination would react with various building materials and furnishings is in need of further study.

Preparedness of Government to Address Challenges of Decontamination

As outlined above, the use of an agent such as chlorine dioxide to decontaminate a building is a complex problem requiring a diverse knowledge base. Consequently, the potential expertise within the government lies in a number of different organizations.(see footnote 3) From an implementation point of view, the following table outlines some particular areas of knowledge and the locations within government agencies where such expertise is believed to exist.

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From the table, it is clear that the expertise to address the problem at hand is not located in a particular agency. Hence, if the problem of decontamination will remain a significant ongoing issue, there is a necessity for some degree of interagency coordination to be developed.

Research Questions and Current Funding

As I have noted, this problem is a complex and multifaceted one. There are some important research questions that remain unaddressed (at least in the open literature). These include the following:

What are the disinfectant concentration-time relationships yielding specific levels of inactivation and how are these affected by temperature, humidity and other environmental variables?

What simulants can be used to determine inactivation of target pathogens? The particular simulant(s) may be functions of the disinfection technology used. Can these simulants be used as reliable ways to verify the efficiency of a decontamination process after execution?

What is the dose-response relationship for human infection/illness with various target organisms and given a desired residual risk level what residual organism level(s) would be acceptable?

What are the decomposition rates of chlorine dioxide and other disinfecting agents in a building environment, and what (if any) byproducts might be produced from these reactions? Are there undesirable effects on materials?

What time lags exist to penetration of a gaseous disinfectant into all interior spaces that need to be disinfected? Can these be estimated by empirical rules or tests? Can sensors be developed to assess gaseous concentrations on a real time basis?

What is the appropriate way in which to deploy verification samples prior to decontamination (both location and number), and what are the practical levels of inactivation that can be verifiably achieved?

As with the execution of a decontamination program, the conduct of research to answer the questions posed above will require investigators (both government and extramural) from a diversity of disciplines, and from a diversity of agencies. The problem posed is one that involves elements of engineering, basic sciences (microbiology, chemistry) and applied sciences and practice (medicine, public health, toxicology, risk assessment). There is no single federal agency with a clear and unambiguous portfolio in all of these areas, and therefore multi-agency coordination in developing the required research effort will also be necessary.

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Concluding Remarks

Mr. Chairman, and Members; I thank you for the opportunity to present my remarks, and hope that they will be useful in understanding and responding to the present situation. I look forward to answering your questions.

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Chairman BOEHLERT. Thank you very much. We will try—we have seven minutes to go before we have to get over to vote. Mr. Barbeito, is that going to be—five minutes going to be sufficient for you? You may proceed.

STATEMENT OF MANUEL S. BARBEITO, CHIEF OF THE AEROBIOLOGY SECTION (RETIRED), AGENT CONTROL DIVISION, U.S. ARMY BIOLOGICAL WARFARE LABORATORIES, FORT DETRICK, MARYLAND

Mr. BARBEITO. Mr. Chairman, and, members of the Committee, thank you for the opportunity to be—

Chairman BOEHLERT. Microphone, please.

Mr. BARBEITO [continuing]. To appear before you. Oh, sir, I am sorry. I didn't hear you. To try to focus on my experience here, I was a member of the Safety Division at Fort Detrick, the highly regarded biological warfare laboratory. And one of the needs of that organization or that facility was to periodically decontaminate all of the facilities, including the pilot plant and production areas, aerosol test chambers, animal holding rooms, and containment laboratories.

Decontaminations were necessary due to agent change, yearly maintenance, conduct major renovations, decontaminations following incidences, either an unknown event, or due to equipment failures.

Ultimately, all contaminated facilities at Fort Detrick were decontaminated, including a terminal decontamination when President Nixon declared that we would no longer pursue biological warfare research in the United States. The facilities that were there were decontaminated successfully and turned over to the National Cancer Institute, which they are being used by currently as we sit here today.

We had many, many different varieties of highly pathogenic agents, including Bacillus anthracis. Now, we will skip numerous things that are in the text. As we all know, we are trying to deal with the issue of contaminated buildings and the cutaneous and respiratory illnesses that have occurred among our population.

The problem that we face is what are the decontaminants that we need to focus on? People on the Panel here have eloquently, briefly described some of the techniques. There are liquid disinfections that can be used, the vaporization of formalin; ethylene oxide is used in its application where it can be applied; vaporization of peracetic acid; vaporization of beta propiolactone; and the last that I would like to focus on is the depolymerization of paraformaldehyde for the formation of formaldehyde gas. This is a technique that we had perfected at Fort Detrick and were successful in using to do large building decontaminations throughout the post.

 The largest building we decontaminated was in excess of a million cubic foot of space. The application to much larger buildings will be a very trying approach. But I think it can be done, in my judgment, as I sit here before you, not having looked at the facilities themselves for that which was mentioned before—each building has a unique characteristic. So you have to assess each and every component of it.

Now, let us just briefly try to address some of the issues that have been raised. What are some of the properties of paraformaldehyde? Its purity is usually between 91 and 95 percent. The remainder is water. It has a flash point of about 200 degrees. I will put in our terminology. It is readily converted with heat to formaldehyde gas. Now, once you get it in the—

Chairman BOEHLERT. Excuse me, Mr. Barbeito. We have just had the warning. So we have only less than five minutes to get over and vote.

Mr. BARBEITO. Oh.

Chairman BOEHLERT. So may we interrupt here—

Mr. BARBEITO. Sure.

Chairman BOEHLERT [continuing]. And we will resume with you as soon as we get back?

Mr. BARBEITO. Absolutely.

Chairman BOEHLERT. And I know the testimony has generated a lot of questions.

Mr. BARBEITO. Okay.

Chairman BOEHLERT. So with that, we will pause now for ten minutes or so to get over and vote, and then get back. Thank you, sir.

Mr. BARBEITO. Okay. Very good. It gives me a chance to breathe.

Chairman BOEHLERT. Thank you.

Mr. BARBEITO. I am trying to rush. Thank you, sir.

[Recess]

Chairman BOEHLERT. We will resume. And I am sorry for the interruption, but that is the business of the House. Mr. Barbeito, you were saying—

Mr. BARBEITO. Not a problem.

Chairman BOEHLERT [continuing]. Before you were so rudely interrupted.

 Mr. BARBEITO. Let me—I don't mind at all, sir. Paraformaldehyde, just to go back over that one, the purity is usually 91 to 95 percent; the remaining being water. It is combustible with a flash point of approximately 199 Fahrenheit, and for those that want it in centigrade, it is 93C. It is readily converted to a formaldehyde gas with some heat.

Now, let us look at the properties of formaldehyde gas. It has an explosive range of 7 to 73 percent. It is—that is percent by volume in air. Now, this is a very wide range for an explosive property of a chemical compound. In our studies at Fort Detrick, when I tried it, once we reached the concentration of seven percent, since this issue has already been approached here, we needed an air temperature of 197 Fahrenheit, 92C, in a test chamber with a spark of at least 20 joules of energy. And that we achieved with a 5,000-volt spark plug.

Now, it also, as you know, is a potential cancer hazard and it is highly irritating, and it is detectable in a lot of people in less than 5/10 of a part

per million. Other people have a high tolerance for it. It is an eye irritant, skin irritant, and ingestion can cause death.

Now, what is the decontamination approach using this? And I will try to be very simplistic in its presentation. And that it equilibrates--if you equilibrate your room temperature at 75 degrees Fahrenheit, plus or minus five, adjust the relative humidity to 75 percent, and you depolymerize 3/10 of a gram of paraformaldehyde per cubic foot of space, in an open container with the heat source--you have to have it controlled no greater than 475 Fahrenheit.

Following the release of the formaldehyde gas through the heating process, you can have a contact time of--which I would highly recommend in the condition of various buildings matrix--of overnight or 24 hours. And depending on the outside ambient temperature, that may be extended.

Now, one of the questions was posed--what about neutralization? By heating ammonium bicarbonate in equal quantity plus 1 percent more, as to the quantity of formaldehyde depolymerized, you can then combat the formaldehyde gas and return the building eventually after aeration to its general, normal use.

A question that was posed here earlier today was how would you use--what would you use as a tracer to determine the effectiveness of a decontamination process? This can be achieved by using the surrogate Bacillus subtilis variety niger spores instead of an actual infectious agent.

One of the things you would need to support this type of an operation is the availability of a biosafety Level 2, and I would recommend going to a biosafety Level 3; so you have a total control laboratory to do the microbiology that is necessary to verify the work.

Now, what is the experience on this? The experience at Fort Detrick, and elsewhere in this country, that I have been involved with would be around 100 or more large buildings that were decontaminated. Now, the ranges were anywhere from, when we were developing this, from a one cubic foot size test chamber that we fabricated at Fort Detrick, up to, as I mentioned earlier, over a million cubic foot of space.

Now, a little bit about historical data. You know, we have had anthrax. It is in, I think, 43 of the contiguous states here, and we have had between 1948 and 1964, nine deaths as reported by the Public Health Service.

And I believe I have in my testimony some actions that I would like to see or would recommend that we, as a Nation take. We terminate the activities in these postal buildings that are contaminated; commence an irradiation program on the incoming mail. But this has to be modified with some prudent decisions as to what is required and how many pieces of mail should go through that irradiation.

You need to do the comprehensive qualitative environmental surveillance program. And what that would entail would be doing air sampling with slit samplers or other air detection device, or using a surface sampling technique--either cotton swabs or the technique of using a RODAC plate, which microbiologists all know, and decontaminate each facility in the manner that I suggest here, or some other appropriate means. And I think there can be a number of approaches here or techniques employed to do the job that the Nation is facing.

One of the things that was mentioned, and I wholeheartedly endorse, is having someone direct the total coordination of the Federal sector to tackle this problem facing us. And maybe Governor Tom Ridge has that authority. I have not heard or seen anything as to how broad his appointment enables him to operate.

And with that, I think, we don't have to go through a summary. And thank you very much. I appreciate it.

[The prepared statement of Mr. Barbeito follows:]

PREPARED STATEMENT OF MANUEL S. BARBEITO

Former Biological Safety Officer, National Program Staff, Agricultural Research Service, U.S. Department of Agriculture; Former Positions at: National Institutes of Health, Occupational Safety and Health Branch, Division of Safety: Biological Safety Officer, Chief Safety Operations Section; National Cancer Institute, Office of Biohazard and Environmental Control: Assistant Safety Manager, Microbiologist; Former Chief Aerobiology Section, Agent Control Division, U.S. Army Biological Warfare Laboratories, Fort Detrick; Biological Safety Consultant

Mr. Chairman and Members of the Science Committee

I wish to thank you for the opportunity to testify before your committee. My appearance is to help assess the feasibility to decontaminate facilities contaminated with or suspected of being contaminated with Bacillus anthracis.

I was a member of the Safety Division at the highly regarded Top Secret United States Biological Warfare Laboratories, at Camp/Fort Detrick, Maryland from 1956 to 1972. The mission(see footnote 4) of the U.S. Biological Laboratories (1943-1972) was: (1) To develop weapons which the U.S. could respond ''in kind'' if attacked by an enemy which deployed biological weapons, and (2) To develop defensive mechanisms against biological attack. A major functional need at the laboratories was to periodically decontaminate the pilot plant production areas, aerosol test chambers, animal holding rooms, and/or the containment laboratories. All of these areas periodically contained Bacillus anthracis as a test agent. Decontaminations were necessary to accommodate changes in pathogenic agents, to perform yearly maintenance, conduct major renovations and decontaminate following accidental release of pathogenic agents due to equipment failure, inadvertent accidents or to combat human errors. Ultimately all containment facilities were decontaminated. The later occurred after President Nixon terminated the Biological Warfare Program in 1969. The facilities were ultimately turned over to the National Cancer Institute.

Numerous pathogenic agents were studied at Fort Detrick including Bacillus anthracis. When anthrax contaminated a building or piece of equipment they were contaminated immediately.

During my testimony, I wish to discuss the overall problem, as my limited knowledge allows, and offer possible approaches to aid the United States to control, eliminate and prevent future biological contamination of the mail, offer a proven approach to decontaminate building and equipment, and briefly cover historical data on anthrax contaminated soils and documented deaths.

PROBLEM

An unknown person or group has chosen to distribute Bacillus anthracis via the U.S. Postal Service. From news reports, anthrax was contained in envelopes as a paste or fine dry powder. As a dry powder, it can readily be aerosolized, which can cause pulmonary anthrax in man. The probable source of pulmonary cases among postal employees was caused by inhaling the aerosol created by letter sorting machines. Cutaneous lesions were probably caused by handling contaminated letters or by touching contaminated surfaces. Several clinical infections and deaths among exposed employees and the civilian population have been reported by the news media. Also, several facilities are presently

contaminated with anthrax spores. However, to my knowledge, no one has attempted to assess how widespread the anthrax contamination is within these facilities nor conduct a qualitative assessment through a surveillance monitoring program.

The problem facing the nation is what to do with contaminated facilities, equipment, the need to continue processing and distributing mail throughout this great nation and how to prevent secondary cross contamination.

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The anthrax problem is causing anxiety, discord, uncertainty and fear among many workers and the civilian population concerned about their safety and health.

Decontaminations

Historically, progression of decontaminations at Fort Detrick were:

by using liquid chemical disinfectants appropriate for the pathogenic agents under investigation. Techniques employed were based on the equipment type and purpose of the decontamination. Techniques were immersion, rinsing, flooding of surfaces, or wipe down of surfaces with toweling moistened with the chemical disinfectant.

vaporization of formalin (liquid) via a steam injection system. An alternate approach was to produce formaldehyde gas through an exothermic reaction by mixing potassium permanganate and formalin.

controlled release of ethylene oxide gas in a ''gas tight'' modified sterilizer to decontaminate sensitive equipment, papers and books.

vaporization of peracetic acid.

vaporization of beta propiolactone.

depolymerization of paraformaldehyde.

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The latter proved to be the most efficient, cost effective, readily achievable approach for large spatial decontaminations.

At Fort Detrick in the mid to late 1960's, studies in Physical Defense and Safety Divisions were performed on the use of paraformaldehyde as a spatial decontaminant. As chief (1960-1972) of Aerobiology Section Division of Safety, Fort Detrick I performed and directed applied research studies to perfect spatial decontaminations using paraformaldehyde.

Properties of Paraformaldehyde and Formaldehyde Gas

Paraformaldehyde-Available as a flake and coarse or fine powder.

- Purity usually 91-95%.

- Water content 9-5%.

- Combustible with a flash point of approximately 93C (199F).

- Readily converted to formaldehyde gas with heat.

- Restricted purchase availability.

Formaldehyde Gas

 - Explosive range 7-73% (percent by volume in air). Our studies showed an explosion would occur when a concentration of 7% was reached with an air temperature of 92C (197F) in a test chamber with a spark plug (ignition energy) of 20 joules (achieved with a 5,000 volt spark plug).

- Potential Cancer Hazard, Occupational Safety and Health Administration Labor.(see footnote 5)

- Highly irritating as low as 0.5 PPM. Some individuals react immediately with respiratory distress, tearing of eyes and violent coughing. Others have a high tolerance to increased concentration in the air.

- Eye irritant.

- Skin irritant with allergic contact dermatitis, ranging from erythema edema and vesiculation or hives.

- Ingestion can result in death.

Decontamination Approach

To decontaminate a room, properly enclosed piece of equipment or an entire building, the following approach was perfected: (see attachment)

- Equilibrate interior temperature to approximately 24C 1B 3 (75F 1B 5).

- Adjust relative humidity to 75 1B 5%.

- Depolymerize 0.3 gram of paraformaldehyde per cubic foot of space. Depolymerization is achieved by heating paraformaldehyde (flake or powder) in an open container at a controlled temperature of 232-246C (450-475F).

- Contact Time-After depolymerization of paraformaldehyde the preferred contact time for exposure of pathogenic organisms to the contained atmosphere of formaldehyde gas is overnight (approximately 18 hours).

- Neutralization-Following the contact period, residual formaldehyde gas can be neutralized by heating ammonium bicarbonate in the enclosed atmosphere. The quantity of ammonium bicarbonate is 1% more than the calculated amount of paraformaldehyde depolymerized. Following the formation of ammonium gas, maintain a minimum contact time of one hour to neutralize the formaldehyde gas.

- Aeration-Subsequently ventilate the building using the heating/air conditioning system.

- Return building to its former use.

MONITORING

The effectiveness of spatial or equipment decontamination can be determined by placing Bacillus subtitles var. Niger spores within the area or equipment. After decontamination these spores would be recovered with subsequent laboratory culturing.

Qualitative surveillance within buildings can be done to determine the extent of B anthracis contamination. Sampling devices can be used to determine if aerosolized anthrax remains in the air. Surface sampling can be done by using cotton swabs and Rodac plates to determine the presence of anthrax on surfaces within the building, and, on/in equipment.

To conduct a comprehensive monitoring surveillance program, and to do effective decontaminations, the support of a local, well-equipped microbiological laboratory would be required. Biosafety level 2 (BL2) containment equipment and facilities are recommended for processing clinical specimens.(see footnote 6) However, to insure effectiveness and efficiency, I recommend using a biosafety level 3 laboratory for monitoring and decontamination. A BL3 laboratory will:

- allow all work to be performed in one central location

- eliminate the potential for cross contamination in the event of a minor accident

- allow work to be done in a biological safety cabinet

- permit sterilization of cultures and materials at a local site

- aid in cleanup

- eliminate concern about cross contamination.

Facility Decontaminations

As a Federal employee I directed and performed approximately 75 to 100 successful decontaminations. Sizes range from 1 to 67,216 cubic feet, (see attachment for details). During terminal decontamination of buildings at Fort Detrick, one of the largest multistorage buildings contained 1,000,730 cubic feet of space. Others were of various sizes and shapes. These decontaminations offered challenges and required ingenuity and tenacity to achieve success.

Historical Data

Bacillus anthracis is a gram-positive sporulating rod found throughout most contiguous states.(see footnote 7) In the past, anthrax has been a modest public and animal health problem. Historically:

- Between 1945-1954, 34 cases of agricultural anthrax occurred in man.

- Between 1915-1945 animal anthrax appeared in 43 states.

- Between 1945-1955: 3,447 outbreaks in livestock occurred in 39 states with a loss of 17,600 cattle.

- Between 1956-1968, the USDA, Agricultural Research Service reported that anthrax appeared in 35 states in 2,571 herds of domestic animals.

- Anthrax occurs occasionally in wild animals, principally deer and elk. Animal anthrax usually does not cause inhalation anthrax in humans. It occurs as a cutaneous (skin) infection that is readily treatable with appropriate antibiotics.

- Between 1948-1964, nine human deaths due to anthrax were reported by the U.S. Public Health Service in the U.S.

- Unfortunately, time restraints prevent a current update of this data but it is probably available from the Centers for Disease Control, U.S. Public Health Service and Agricultural Research Service, U.S. Dept. of Agriculture.

Urgent Actions

In my opinion, actions beyond those which have already been done must be

performed immediately.

Terminate all activities in postal and other buildings where anthrax contaminated letters have been sorted or handled.

Commence an immediate irradiation program for all letters and packages handled by the U.S. Postal Service.

Conduct a comprehensive qualitative environmental surveillance program in each contaminated facility.

Decontaminate each facility as outlined in this testimony or by some other proven technique.

A person, with ample staff, must be appointed with broad assigned responsibility and authority over many government agencies to implement immediate corrective actions. Delays will perpetuate and proliferate the contamination problem. The recent appointment of Governor Tom Ridge as Director of Homeland Security may be a start to correct delayed actions.

Unless corrective actions are taken, the United States will: (1) continue to experience occasional cutaneous and pulmonary anthracis among exposed people, and (2) additional facilities will become contaminated throughout the United States.

Summary

United States has experienced distribution of a deadly, stable pathogen, Bacillus anthracis via the U.S. Postal System. Other pathogens could similarly be distributed via the same or other mechanisms. Economic losses will continue to occur. Clinical illnesses and deaths could continue unless immediate corrective actions are taken. Namely:

Decontaminate existing contaminated facilities by using proven techniques and procedures (e.g., depolymerization of paraformaldehyde).

Irradiate all mail to prevent the re-introduction of the same or different pathogens.

Establish isolation parameters immediately for a suspect or new terrorist act to prevent widespread cross contamination and exposure of personnel.

Establish rapid detection and monitoring regiments.

Implement prompt decisive, authoritative control measures.

The above actions will help immensely in reducing anxiety so that the U.S. citizens will again enjoy the peaceful, stable, harmonious living that we are accustomed to.

Thank you

Discussion

Federal Coordination

Chairman BOEHLERT. Thank you very much. I appreciate it. I don't like to make assumptions, but let me ask you, is there any disagreement with the basic thesis that there does not appear to be any central focus point for the activities we are discussing with the Federal Government? There are several agencies involved doing different things.

But as this whole picture is evolving, we still don't have—at least, my perception, and I would like to be advised if this is not correct—we still don't seem to have a coordinating central focus point. Is there any disagreement with that statement? Is there any agreement on where you think—and let me ask each of the panelists—there should be that centralized focal point for activity. I am convinced that the government is doing a lot of things in a lot of different places that are very valuable and very important. It is just that the coordination is somewhat questionable, and the focal point for that is questionable. Dr. Goldman—and let me ask each of you, what you think of that assertion.

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Dr. GOLDMAN. I agree with the assertion and I personally think that the focal point ought to be within the Department of Health and Human Services for a clean-up effort, and that it needs to involve multiple agencies. However, there needs to be the authority to coordinate efforts of EPA and the military, who have much expertise in this area, and also OSHA—

Chairman BOEHLERT. Okay.

Dr. GOLDMAN [continuing]. And probably the Department of Energy, as well.

Chairman BOEHLERT. Dr. Baker.

Dr. BAKER. I would differ a little bit on that. I think there are already coordinated efforts between DoD and DOE in this regard, and they have really taken the fore—they, for some reason, have not been involved in the current issue up on Capitol Hill, but certainly they have done most of the research and coordination for efforts like this, particularly as it relates to Olympic events or things like that.

HHS needs to be involved because the consequence of this is medical. But they probably aren't the coordinating agency for the clean up itself.

Chairman BOEHLERT. Dr. Haas.

Page 91 PREV PAGE TOP OF DOC Segment 1 Of 2 Dr. HAAS. I agree that there needs to be coordination. I guess I am not totally sure that HHS necessarily—and it is ironic in that EPA originally started out as a public health agency. And, in fact, many of the early people that went into EPA were commissioned Public Health Service officers. You know, to my mind, it would be nice if they rediscovered that mission. But I don't really have a strong opinion, other than that, in terms of where a nexus should lie.

Chairman BOEHLERT. So there might be some difference between your view and Dr. Goldman's, for example. HHS and you say EPA. The point is, there needs to be one.

Dr. HAAS. Exactly. Exactly.

Chairman BOEHLERT. Where it is clearly there is—

Dr. HAAS. Exactly.

Chairman BOEHLERT [continuing]. The buck stops at somebody's desk.

Dr. HAAS. Yes.

Chairman BOEHLERT. And I think they are actually working on that right now. And, Mr. Barbeito.

 Mr. BARBEITO. From what I understand from the paper--because I haven't been briefed on any of this--there needs to be some authoritative person who is the ultimate person who can say you will do ''A,'' ''B,'' ''C,'' and ''D,'' and you need the coordination to pull together the government agencies.

Now, Dr. Goldman has hit it on the head, I think, and pretty much along my line of thinking. That Health and Human Services has the expertise within the biomedical community as to how to decontaminate. This technique that I have described is not something that died at Fort Detrick. It is used worldwide. We, in the United States, perfected it, but we didn't keep it because it was done with public money.

Decontaminating the Hart Building

Chairman BOEHLERT. You said the building you decontaminated had a million square—

Mr. BARBEITO. A million--over a million—

Chairman BOEHLERT. Was that sort of a—

Mr. BARBEITO. It should be feet.

Chairman BOEHLERT [continuing]. Warehouse situation?

Mr. BARBEITO. No, sir. It was a research laboratory.

Chairman BOEHLERT. Oh.

Mr. BARBEITO. A Level 4 containment—

Chairman BOEHLERT. So one could argue that it would be comparable, for example, to the Hart building. In other words, it wasn't just some big warehouse. It held—

Mr. BARBEITO. No, sir.

Chairman BOEHLERT [continuing]. Individual offices and—

Mr. BARBEITO. It had offices. We had--on a terminal decontamination, we did from the basement level to roof level when we decontaminated the buildings at Fort Detrick, to make sure, to the best of our ability, they were safe for human occupancy once we—

Chairman BOEHLERT. And, as you understand what--all of you--what they are doing with the Hart building--and do you agree that it was right to put a halt to it and look at a different approach than the initial approach they were thinking in terms of? I understand that posed a number of problems. And now they are going to do it selectively with a particular emphasis on the ventilation system and two of the senatorial offices are going to get one treatment and other areas of the building another treatment. And then there are going to be spot tests. But are you confident that they are now on the right track with a way to do that, or do you have any suggestions you would offer? Dr. Goldman.

Dr. GOLDMAN. I do think that it was a good thing that they took a step back and took, I think, a more analytical approach to the problem. I think that we want to feel--all want to feel--that all of the alternatives were carefully assessed, kind of in the way that all of us laid out here, in terms of efficacy

and safety. It wasn't clear that that was done initially. But that is something that you would wish to have done. In terms of the details of how they are doing it, I am not familiar enough with the details to be able to comment on that.

Chairman BOEHLERT. Anyone-Dr. Baker?

Dr. BAKER. I think one of the things that drove this was the expectation placed on them that they would sterilize this building. And they were going to technical extremes to try and do that. I think the rationality is that you aren't going to sterilize the building no matter what you do. You should do something that is technically safe and achievable, look at the residual, and proceed on that basis. And I think they have been very concerned about the ventilation system because they view that as a source for reaerosolization of spores. No one really knows that. And they really need to document what is left after they clean it up.

Chairman BOEHLERT. Well, you-well, there are other people. I will get back. Any other comments? And I could go on just monopolizing this. That is not fair. I will let you complete the answer to this question and I will go to Mr. Hall.

Dr. HAAS. No. I would simply say that, you know, like it or not, what is being engaged in is a research project. And I think the way in which you run a research project is you do it in stages. And so to look at a small portion of the building and examine what the results are is eminently prudent, rather than to attempt to do the whole—

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Chairman BOEHLERT. So, in essence, the Hart building would be a laboratory.

Dr. HAAS. Yes. Yes.

Chairman BOEHLERT. Mr. Barbeito.

Mr. BARBEITO. I don't know what approaches they are taking as yet. To address the ventilation system, I would say that the expertise or the experience at Fort Detrick is that we decontaminated all of the ventilation systems there, along with the rest of the building. It was just an integral component of it. This technique of doing ventilation systems is used in the biomedical community throughout the Nation.

Chairman BOEHLERT. But you keep referring to this. What was the contaminant?

Mr. BARBEITO. The contaminant was any infectious agent used at Fort Detrick. Now, I think how—

Chairman BOEHLERT. But you had no clearly defined—

Mr. BARBEITO. No. Wait.

Chairman BOEHLERT [continuing]. Contaminant-anthraxes or—

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Mr. BARBEITO. Yes. We did.

Chairman BOEHLERT. Oh. You did.

Mr. BARBEITO. Many of the buildings that we decontaminated had inadvertent release of anthrax due to various reasons. We can go into them if you would like. But just suffice to say, we had anthrax-contaminated buildings that we successfully eliminated. Now, how did we know we eliminated it? We used the monitor, Bacillus subtilis variety niger spores to determine the effectiveness of the decontamination approach. And we also went back in and tried to recover anthrax from those locations which we had previously identified as a release

within the building. But we have the direct experience of trying to address how do you get at anthrax.

Now, if you look at ventilation systems-sorry to be so long-but the exhaust from test chambers at Fort Detrick went to air incinerators. That exhaust system had to be decontaminated, along with the test chamber. And that was done with formalin, where we used the vapor particle to decontaminate those. And we would sample those periodically along with the filter systems on these buildings. This is-in the early days, was a 50FG, fiberglass filter media, or, today, it is the HEPA filters.

Chairman BOEHLERT. Okay. Thank you. Mr. Hall. And then I have got 150 other questions. But we are going to try to stick to the time limit. Mr. Hall.

When Is a Decontaminated Building Safe?

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Mr. HALL. I think I have heard what you said, each of you, that on-and the fact that it is a research program kind of hits the spot pretty well. It is similar to a lot of other of our legislation, that is trial and error. We-of course, like the law, you know, all lawyers think they know what the law is, but the Supreme Court gets the last guess at what the law is. And you all are about ten guesses ahead of all of us.

And I have one question that might relieve a little of my amazement at all of it. It is my understanding that the decontamination, as we understand what it is, absolutely won't kill all of the viruses or all the spores in a building, and that is probably an impossibility. How do we know when the building is safe-now, that is part of the research program-where we can re-enter? Who is capable of making that decision for the American people? Just-in the good general question. You get last guess at that question.

Dr. GOLDMAN. I will start. I think that how you know-I mean, first you do need to have defined a level of contamination that is considered to be, you know--

Mr. HALL. Acceptable?

Dr. GOLDMAN [continuing]. Acceptable. And that will require bringing together experts in microbiology and in infectious disease in order to do that. I think you want to have that kind of a process.

Mr. HALL. How long would that take?

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Dr. GOLDMAN. I think it could be-I don't think that it is a long-term process. I think it is a matter of getting the experts together to do it, which nobody has done. I think it could be done in days.

Mr. HALL. What is a long-term process?

Dr. GOLDMAN. I don't-I think it could be done in days if people-because I-at least so far, in my experience with this problem, everybody I have called to ask for help has been immediately available, regardless of how busy they are. People view this-scientists view this as a national security issue and they want to help. So I think you could get people within days if you-if there were a process for them to plug into. Maybe the Institute of Medicine could do that.

The other thing it has to do with then, if you have a target for what is a safe level-how do you do scientifically valid sampling of a building-both the surfaces, the air, the HVAC systems-to say that the building meets that? And that is also something that could be put together in very short order, but you need the experts, people who understand how buildings operate, engineering

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systems in buildings, movement of particles in buildings, and the models for that. That is available. But those people would need to be drawn together to do that. It could be done on very short order.

Mr. HALL. Do the other three of you generally agree with what she said?

Page 99 PREV PAGE TOP OF DOC Segment 1 Of 2 Dr. BAKER. I would generally agree that you could rapidly come to some type of consensus. The problem is now that no one is willing to make a statement because there is no total assurance in this. And I think whatever you say you have to go with the post-decontamination monitoring to make sure that there aren't hot spots that you missed that are going to re-aerosolize, and to make sure that people, if they have symptoms of something that looks like anthrax, are taken care of appropriately.

Mr. HALL. Mr. Barbeito, I think you had your hand up. Mr. Barbeito.

Dr. HAAS. The-I would just-you know, I agree with everything that Drs. Baker and Goldman said. The only thing I would add is ultimately an acceptable risk level is a public policy decision. And so with some level, through some mechanism, I would suggest the public, either directly or through their representatives, need to be at the table, as well, to help factor in what standard we use.

Mr. HALL. Yes, sir.

Mr. BARBEITO. In the veterinary and biomedical fields, the accepted concentration to determine is something safe for reuse in open settings has been established at 1 times 10 to the 6 spores per ml of original concentration that is seeded throughout the buildings. This is used, according to world health. So I concur with what you are saying, and it can be done promptly. But this is what we have established. It was originally done at Fort Detrick and has been adopted.

Page 100 PREV PAGE TOP OF DOC Segment 1 Of 2 Now, I hate to sound, you know, arrogant here with a statement that factual, but that is what we used. And if you went to CDC, for instance--

Mr. HALL. I guess you have to use what you have and what you have tested.

Mr. BARBEITO. Yes. And this is the experience. The experience has dictated if you have a contaminated building, you use this as a test with the spore I mentioned, and at that concentration we have not had subsequent infections or problems. We have not had--

Mr. HALL. Now, we have known about anthrax for years, those of us that deer hunt. And--

Mr. BARBEITO. Right.

Mr. HALL [continuing]. You go to the deer camp and you kill and skin a deer and cut him up, him or her up. Why, you wash your hands and really try-I have even seen people-and it always made me mad-that poured Jack Daniel over their hands, you know, when they--

Mr. BARBEITO. But the alcohol is a good disinfectant, sir.

Mr. HALL. Yeah. But it can make you so much smarter if you will use it some other way. Let me ask Dr. Baker-and I know my time is up. I will be quick. Doctor, I understand you have developed with the DARPA funding what people say and have been judged as a fairly effective anthrax disinfectant. And I think you

The Decontamination of Anthrax and Other Biological Agents.txt pointed out, maybe in your executive summary here, that performing best in the overall rankings were University of Michigan, Sandia National Laboratories, and Livermore. Were those your-was that your work? I mean, just cast modesty to the wind and--

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Dr. BAKER. Yes, sir.

Mr. HALL. Okay.

Dr. BAKER. I mean, one of the things we were charged by DARPA was to develop a broad spectrum disinfectant that would take care of all the Australian list agents, while at the same time being safe to use, even on people. And our material is different. It is not an oxidizer like most of the anti-spore agents. It actually induces the spore to start metabolism and then kills it as it sort of ramps up. So you kill it before it ever becomes a bacteria and can be infectious. And because of this, you don't have to use many of the toxic chemicals other disinfectants employ.

Mr. HALL. And with a yes or no, in a side-by-side comparison with other disinfectants, your product was ranked very high and maybe number one.

Dr. BAKER. It was.

Mr. HALL. Yes. And then, is your product being used here on the Hill?

Dr. BAKER. They have requested it. We have not--

Mr. HALL. Just give me a yes or a no.

Page 102 PREV PAGE TOP OF DOC Segment 1 Of 2 Dr. BAKER. Not yet. No.

Mr. HALL. And now tell me why.

Dr. BAKER. We-they have requested it and we have not quite felt comfortable with the conditions that they were prescribing for use.

Mr. HALL. And you have asked for a waiver.

Dr. BAKER. We are in that process. It is clear that they would provide a waiver, but it is not clear what that waiver would waive us from.

Mr. HALL. But that is something that gives us hope.

Dr. BAKER. Yes. I am hopeful that-part of the problem is one part of the government will do something and another part will react to that in a different way. And we are trying to coordinate, particularly in the EPA, that if we provide material to them under an emergency approval process, that other portions of the EPA won't hold this against us in further evaluation for other applications.

Mr. HALL. So if they use yours, it is acceptable, it is workable, we have something to be happy about. And you could logically answer the question that Regis asks them about three nights a week. Could you not?

Dr. BAKER. Yes. We probably could.

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Mr. HALL. Would you like to be a millionaire? Mr. Chairman, I have some more questions I want to ask, but I will yield back now.

Chairman BOEHLERT. Okay. We all do. But your line of questioning focuses on one thing-safe for whom? It is not going to be one size fits all. If you are more mature, as Mr. Hall and I are, it might be one standard. If you are younger or if you are pregnant, or-there are several variations-but I wouldn't anticipate a safe designation that would apply to all.

Mr. HALL. What if you are both old and pregnant?

Chairman BOEHLERT. Then you go to the Jack Daniels. Mr. Smith.

Bridging the Gap Between Basic Research and Application

Mr. SMITH. Thank you, Mr. Chairman. I think, just listening to your comments and a lot of the questions that you really are asking-my first question would be, what can Congress do, or what should be done to sort of bridge the gap between the truly amazing basic research that exists in a lot of our laboratories, such as yours on the nanoemulsion, Dr. Baker, to bridge that gap in terms of making it more quickly, useful, and available?

I mean, NSF has immediately, in the first week after the September 11, started a direction of sequencing the genome of anthrax. I mean, those kind of things are very effective. We went in and we came out with the-some engineering tools that we had done basic research on and sent them up to-in little robots, into the ground zero in New York. But your comments on maybe what we should be looking at in terms of better using some of the knowledge and information and tools that are out there in our laboratories to make them more available to the general public and to Congress. Dr. Goldman-and let us-just maybe a quick comment right down the line.

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Dr. GOLDMAN. Yes. I will go quickly. And I think the-your major role obviously is oversight. Somebody mentioned the Challenger Commission. I would say that the real analogy is here, in terms of science that has been available and has not been incorporated into the decision processes-because of the way that sometimes decisions are made and the way that operations are sometimes run in a critical situation.

And I think in your role, in terms of oversight, you know, pushing the science into the decision process and pushing coordination so that the parts of the government that have knowledge that is necessary are engaged in the decision process. You can be very powerful there.

Mr. SMITH. And maybe expand-and I would use that for the other three witnesses to maybe expand your answer in terms of somehow getting the information and research that DARPA has back to our other research and maybe vice versa. Dr. Baker.

Dr. BAKER. It is a very difficult thing, particularly for biologic applications. That is for two reasons. Number one, there is no real transition program in DoD that takes the basic research or for that, in almost any government program for biology and transitions. That has been traditionally the purview of biotech or pharmaceutical companies. There needs to be almost an Advanced Technology (ATP) program for advanced technology for biology, understanding not only that you have to develop the technology, but the amount of regulatory approval for human use or use in conjunction with human beings is really tremendous and can run hundreds of millions of dollars.

Page 105 PREV PAGE TOP OF DOC Segment 1 Of 2 Mr. SMITH. Dr. Haas.

Dr. HAAS. Well, from my perspective, I would point out the one barrier that does exist is this-what has to be done is the interface between biology and

engineering and other disciplines. And NSF is the traditional funding arm of a lot of engineering research. On the other hand, NSF is basically precluded from doing direct health-related work. And so some how or other there needs to be a bridge of that barrier.

Mr. SMITH. Mr. Barbeito.

Mr. BARBEITO. I wouldn't have anything further to add to what was--

Detection of Agents

Mr. SMITH. It is, you know, somewhat disappointing in the defense authorization bill of '97, '98, and '99. We put in language to-that there was a sense of Congress to aggressively pursue detection in terms of our troops. And the Committee review was disappointing in terms of what has been done in that area. But certainly, detection has got to be part of the effort. Where are we on detection? You sort of-some of you sort of referred to it, but, Dr. Goldman, and then maybe down the line.

Dr. GOLDMAN. Well, I think that one issue is that the modes and the processes that you might use for detection in a battlefield are different than what you might want for a building and for a system like the mail system. And so that-and I can't really comment on what progress the military made in terms of battlefield. But I would say that you would need a different kind of approach to the research for thinking about, you know, complicated buildings and so forth.

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Dr. BAKER. In one of my other hats, I have sat on the Terror Review Board for Chem-Bio for the DoD. And I would agree with your assessment. And I think you bring up one point-the fact that the technologies we have developed for regular laboratory use just don't work in the field. These miniaturized PCR units work wonderfully in the laboratory, but you get them dirty out in the field and they just, you know, die. And--

Mr. SMITH. And that would include the Department of Energy's detection instruments that they—

Dr. BAKER. Well, I won't go into specific applications, but it is a general problem with the technology. But the other thing, too, is that most of these technologies don't differentiate between live and dead organisms. And particularly, when you are doing gene-based analysis, you can have organisms that are dead, but are still detectable by this route. So there is a real need there to be able to differentiate.

The other problem is that they are based on identification of specific antigens or genes. And one of the things we are concerned about with our enemies, they have developed organisms that have deleted those or modified them so they can no longer be defended against or identified.

So you are right, there are numerous problems in this. And, for some reason, the translation of that over to troop-based protection has not occurred.

Dr. HAAS. I would identify the issue as being one of sample preparation. A lot of the basic techniques derive from the clinical field where essentially a diagnostician knows what he or she is trying to look for at the point when the test is being done. In environmental analysis, very frequently you don't know what you are trying to look for and so the objective is to clean up everything else away from something you are trying to see.

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And while there has been a lot of attention devoted to measuring something in a laboratory at the end, there has been relatively little attention devoted to sample preparation and concentration and clean-up.

Mr. SMITH. Yeah. Mr. Barbeito.

Mr. BARBEITO. I will, you know, agree with what has been said about rapid detection. But looking at-and to twist this back around a little bit-what is the potential level of contamination in these post offices or the Hart building? The issue is, do we need to assess any further or assume-just make the assumption that we do have contaminated buildings. Because people have become sick.

And if you went in there, you could do the air sampling that I mentioned, or surface sampling, and try to determine, okay, here are the areas where we have contamination. But you still have to treat the entire building. And once you do a sampling program, you then reaffirm, okay, we do have anthrax. We do have to clean these buildings up so they can be reused. A variety of techniques, in my mind, will probably have to be applied here.

Mr. SMITH. Do we have good knowledge-and my time is up. Do we have good knowledge on how safe is safe? We have tended to say that if it is detectable, boy, it is unsafe. Should we be saying, here is the level and here are the related risks to this level?

Chairman BOEHLERT. That is not a scientific you just said-that is a political decision, really, quite frankly. I mean, you can give us the science and can say, under these conditions, 1 in 10,000 are at risk or—

Mr. SMITH. Do we have the knowledge—

Chairman BOEHLERT.-1 in 15,000?

Mr. SMITH. Yeah. Sort of. Do we have the knowledge to say-to detect-to determine that level of risk?

Chairman BOEHLERT. Dr. Goldman. And then we will go to Ms. Rivers—

Dr. GOLDMAN. Yeah. I mean, there are—

Chairman BOEHLERT [continuing]. Because your time has—

Dr. GOLDMAN. There are two basic ways that people try to approach that. One is the risk-based approach, which is-and I am not sure that we do have the knowledge to use a risk-based approach. And the other is an approach that would be based more on feasibility/delectability, a de minimis, if you may, approach. You would need a panel of-you know, a large panel of scientists to really be able to answer your question. But, from what I have seen, I have doubts that a risk-based approach is feasible right now.

Chairman BOEHLERT. Thank you. Your time has expired. Ms. Rivers.

Ms. RIVERS. Thank you, Mr. Chair. Dr. Baker, I have a couple of questions for you. We had a briefing last week from a panel of three, and Ken Alibek from the Soviet-former Soviet Union was there. And it was a very sobering discussion and lots of information came out. And he was talking about that, yes, we now have-we are dealing with anthrax, but there are things like plagues, smallpox, Ebola, Q fever, out there. Do you have any sense whether the product you have would work in those circumstances?

Dr. BAKER. One of the keys or one of the givens, since several people, including Mr. Alibek, have informed us of the activities of the former Soviet Union, is that we can't rely on conventional measures all the time. You can

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imagine how bad this outbreak would have been if you were dealing with an antibiotic-resistant form of anthrax, which clearly is present in the Soviet Union, along with antibiotic-resistant plague. Our material was developed to handle this in a non-specific matter, so those things would not be an issue.

But I think that is a major concern. You know, they have made these organisms resistant to most of our conventional therapeutics, and, in some cases, have made them so they will overwhelm our vaccines. So there are reasons to be very concerned about that. We believe that we may have a potential solution for that, and that is part of the reason we have been pursuing it.

Barriers to Production and Distribution of Decontamination Technology

Page 110 PREV PAGE TOP OF DOC Segment 1 Of 2 Ms. RIVERS. Well, I want to follow up a little bit on what Representative Smith was talking about, because I know that there are folks out there with good products that have been—or good ideas that have been developed either at universities or in the private sector. And they are having difficulty bringing them forward. What do you see as your barriers to production and mass distribution? And what can Congress do about it?

Dr. BAKER. Quite honestly, this probably will not be a marketable product. You know, my hope is that we resolve this and the people or persons who are doing this are apprehended and we don't have to worry about this in the near or distant future, except for some reserves. And, unfortunately, the way we formulate this material, it will require individual regulatory approval for this particular application. And you cannot get commercial support for that.

If we are going to have to, as a country, to develop defenses that are unique to these types of situations, we are going to have to do it on a governmental level. I was actually—you know, I mean, we have a 7,8 person company that is trying to deal with this and, you know, trying to find the funding to proceed, because we want to make this available.

Ms. RIVERS. Uh-huh.

Dr. BAKER. We owe a debt to DARPA for supporting the basic science. But I was somewhat amused to see Pfizer and several other large pharmaceutical firms that were saying that they won't pursue any applications for this because they don't view them as financially viable markets.

Page 111 PREV PAGE TOP OF DOC Segment 1 Of 2 So I think, clearly, getting the types of approval, I mean, just to provide material on the Hill, will sort of key us in—under emergency approval from EPA, will key us in to about a $5 million process to go back and redo all the appropriate studies with EPA so that we can show that the emergency approval they gave us was okay. And, you know, I am more than happy to provide material, but I think that is a high cost.

Ms. RIVERS. Well, I hope you are right that we are not going to need this in the future, but I think that is a scary assumption. And I am worried that there are other things that we will need in the future that we will not be able to get. I understand what you're saying—the pharmaceutical companies don't like to do this sort of thing. They don't like to do vaccines because it has a limited sales potential. But is it—would it be reasonable, do you think, to set up something like the orphan drug program where we recognized that the government pays the cost, because the drugs are so important to a very small group of people, but they still can't be stopped. Would that be a model that might work?

Dr. BAKER. I mean, if you look rationally at the number of people who would be at risk for anthrax, that actually would fall into the orphan drug group. You

can't use that for disinfectants because it is not a medical purpose. But, you know, particularly if you were doing something specific, I think you might be able to go that route as a preventative type thing for these problems.

Ms. RIVERS. Dr. Goldman.

Dr. GOLDMAN. Another analogy is something called the IR-4 program, where the Department of Agriculture develops pesticides for crops that have a small market share, and, therefore, are not supported by the large pesticide companies. But there is no public health equivalent of the IR-4 program, whether we are talking about bioterrorism or West Nile. There is no public health equivalent.

Ms. RIVERS. Thank you. Thank you, Mr. Chair.

Chairman BOEHLERT. Thank you very much. Dr. Bartlett.

Relative Risks and Diminishing Returns

Mr. BARTLETT. Thank you very much. I have a new device that I would like to introduce to the market, I think, that would revolutionize the way we do things. I think it would be enormously valuable to our society. But I need to tell you that there is a potential for maybe as many as 50,000 deaths a year and hundreds of thousands of life-altering consequences as a result of the use of this device. But I will tell you that society, I think, will find this device very acceptable. That it would find widespread use in our society. What chance do you think I have of introducing that device to the market? Dr. Haas, you—

Dr. HAAS. Is your name Henry Ford?

Mr. BARTLETT. Sir?

Dr. HAAS. Is your name Henry Ford?

Mr. BARTLETT. Yeah. Of course, I am talking about the automobile, which we never would get on the market today. And the reason I use this analogy is that if we wanted to avoid the risks involved with using the automobile, you would use a tank to go around the corner to the convenience store to avoid this risk. And my concern is that what we are going to require in decontamination of these buildings is the equivalent of a tank to go around the corner to the convenience store.

And we are never going to totally decontaminate, probably. And you will reach that final stage asymptotically, with the last benefits, with the last improvement enormously expensive and time-consuming. And I am wondering, how can we decide when enough is enough. And, you know, today, 120 people will die in auto accidents. Sixty of those will die from drunk driving. Sixty people will die today from influenza. And I don't see people running around with a mask on and avoiding the mall because today 60 people will die from influenza which you will catch out there. How do we decide enough is enough and life has to go on, and we can't aid and abet the terrorists by shutting down our society on unrealistic expectations?

Dr. HAAS. I would give you a more direct analogy. According to CDC, there are 5,000 deaths due to food-borne illness per year.

Mr. BARTLETT. Due to what?

Dr. HAAS. Food-borne illness—food-borne infectious disease.

Mr. BARTLETT. Okay.

Dr. GOLDMAN. I don't think that there is an easy answer to your question. You don't want the cure to be worst than the disease. I mean, that is a fundamental principle, you know, in medicine and in public health. So certainly you want to be sure that whatever you are doing is an improvement over the risks that—

 Mr. BARTLETT. There is an old farm saying—

Dr. GOLDMAN. Right.

Mr. BARTLETT [continuing]. That the juice ain't worth the squeezing.

Dr. GOLDMAN. Right. So it has got to be worth it.

Mr. BARTLETT. And I am afraid that is where we may be going here.

Dr. GOLDMAN. Yes. You can reach a point of diminishing returns in analysis. And I think that is the point that you are making, and you certainly can. And you hit a point where you need to do something. And that is where-and I had raised this in my testimony-the issue of the urgency and-of actually getting back to business becomes an issue. And time is an issue. And that is something that has to be factored in a decision.

Mr. BARTLETT. Dr. Baker.

Dr. BAKER. Again, this is somewhat of a political issue. But I think if you tell people what the rational risk is, and if you come to that through an appropriate analysis technique, and assure them that they are going to be supported if they feel that they are at risk, and there are any follow-up problems, you are going to be able to accomplish that. People can deal with risk as long as they understand what it is and they are given appropriate support to deal with it.

And the problem right now is that they are being told nothing and everything, and it has created a tremendous distrust. And moving forward, that is going to be something that will have to be overcome before you can actually start building a relationship with these employees that will allow you to monitor them and make sure that they are okay.

Mr. BARTLETT. But that is very tough to do because they didn't tell me what the relative risks were when they threw me out of this building. You know, I would have chosen to stay here, because I didn't think the relative risks were worth throwing me out of here for five days. But we are not giving our citizens that choice. I couldn't agree with you more that we need to educate and then the citizens will use their good judgment as to what they want to do. Mr. Barbeito.

Mr. BARBEITO. I would view it as offering the public the best available technologies we have to decontaminate buildings and tell them, this is the best we have. We have data to support reoccupancy of buildings that have been contaminated and decontaminated with processes that exist today; and that many of us are here, I, included, have been in contaminated buildings and situations. And we-and I have been effective in decontaminating these buildings then we have reused them.

And I think an attest to this is the contaminated buildings at Fort Detrick, because there is where the greatest database is, that the people are living there, working there, every single day in the Cancer Institute buildings that were once contaminated with anthrax and other infectious agents.

Page 116 PREV PAGE TOP OF DOC Segment 1 of 2 You-the one that was just mentioned, the list that was mentioned here-Ebola, for instance, is used, right as we sit here today in USAMRIID at Fort Detrick. They decontaminate those. The people go in with protective gear. But once it is de-conned, they do go in and do renovations of those spaces. And I think that is a test as to the technology and the capability that we have that people have to accept, that needs to be explained-this is what you are getting, the best we have to offer in this country. And it is no better, no worse than anyone else uses in the world.

Mr. BARTLETT. Mr. Chairman, there is one building at Fort Detrick that is seven stories high that is still boarded up because it has been decontaminated, but there are some people who are afraid to use it. I am volunteering to go through that building with Mr. Barbeito. And he believes it is safe. If he believes it is safe, I think it is safe. And I want to send a message to the American people that we know how to clean things up, and enough is enough. So, you know, I am going to ask NIH, the National Cancer Institute, if they will open those doors so that we can go through that building to prove to the American people that a once highly contaminated building can be decontaminated and it is safe to go there. Thank you.

Chairman BOEHLERT. Dr. Bartlett-Mr. Hall-if you are looking for additional volunteers for that mission, Mr. Hall wants to volunteer his opponent. But if we-let me-Mr. Barbeito, let me ask you, at Fort Detrick, when they went back in after the buildings were decontamination, were they vaccinated? Were military treated differently than civilians? Were all treated in a like manner?

Mr. BARBEITO. After decontamination, there was no requirement for vaccination if you were a new person coming in and it was a newly cleaned-up building and it wasn't going to be used for infectious disease research.

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Chairman BOEHLERT. Thank you. Mr. Moore. Mr. Larson.

Regional and Local Response

Mr. LARSON. Thank you, Mr. Chairman. Last week we heard testimony from Dr. Smithson. In reading some of the literature, one of my concerns is, with regard to decontamination, the need for regional and local response. What would you recommend to regions that are now preparing-and let us say, hospitals or front-line, first responders, et cetera? What are the steps that communities should be taking with regard to being first responders? I will start with Dr. Goldman.

Dr. GOLDMAN. Well, I absolutely agree that you do need to pay attention to the first responders and the community around. That you need to make sure if you have got materials that are hazardous that they are being appropriately transported, stored, and handled by everybody. And you can't be in such a hurry that you do shortcuts on that. And then probably the emergency medical system needs a briefing from people who understand what the materials are, what to expect in the way of acute and chronic effects, how to treat people. If-and, by the way, how to protect themselves if they have to go into a situation.

I mean, one of the things that I found to be very sobering was learning that the Capitol police themselves, who are some of the first people to come into, obviously, a room like this if there is a problem, they are not trained as first responders. They are not trained in the use of respirators. They are not trained in the use of personal protective gear and they do not know how to identify hazards. And so you need to have all of that in place if you are going to do this. And depending, of course, on the materials that are involved.

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And that is where, actually, I think the folks at the EPA, the emergency

response people there know that very well. There are emergency responder systems throughout the country where the state and local-level people know these very well. But you are need to make sure that they are in the loop, that they are a part of the process, and, oftentimes, they are not in the loop.

Mr. LARSON. Dr. Baker.

Dr. BAKER. The CDC has organized a network that, I think, has been fairly effective in coordinating these events. I will say that the weak link does appear to be before the hospital in most cases. And, in fact, when you look at some of the exercises that have been conducted, particularly in New York in the subways, the problem was that all the first responders contaminated themselves in their efforts to try and help the people. And because it was a contagious agent, it basically exploded the area of containment so that they had to basically cordon off the whole City of New York, whereas before they had a small site.

So the real issue is training and coordination of the people who are going to be initially involved in responding, particularly for containment. Containment is a crucial thing. And if we have a large-scale release, let us say at a sporting event or another public event, trying to mediate containment in a very scared and disorganized population will be an incredible effort. If we don't do that, though, essentially, we have become the disseminating force for the bioterrorists.

Mr. LARSON. Good point. Dr. Haas.

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Dr. HAAS. I have nothing to add.

Mr. LARSON. Mr. Barbeito.

Mr. BARBEITO. For the first responders, I think the key that has to be adopted is a correlation that we use in the infectious disease laboratory. Whenever there is an incident, people have to just step back. If it is a biological agent, step back a moment and give it a minimum of 20 minutes, preferably 30 minutes, for the aerosol to settle. Once that aerosol settles and you have the first responders that Dr. Goldman said, you put them in protective gear. You limit the spread of this dissemination. And so, as Dr. Baker stated, you don't become the foci for movement of it beyond the initial site. You try to contain it at its least geographical area.

And I think the first responders have to have the Tyvek suits readily available, which are inexpensive. I am not a commercial person. And then you use respiratory protection for the first responders. I think this is critical that we get this information, these packets available, for these people.

Mr. LARSON. Thank you very much. And I yield back.

Chairman BOEHLERT. Thank you. Dr. Ehlers.

Public Perception of Risk

Page 120 PREV PAGE TOP OF DOC Segment 1 of 2 Mr. EHLERS. Thank you, Mr. Chairman. And you would probably be able to tell that both Dr. Bartlett and I are scientists because our comments are going to be quite similar. I would—and, Dr. Baker, you made the comments that people can deal with risk. And you have much more confidence in that than I do. I mean, maybe you deal with more intellectual people or—than I do. But certainly not to insult the people that I—

Chairman BOEHLERT. Are you talking about your colleagues, Dr. Ehlers?

Mr. EHLERS. No, sir. And I am not insulting my constituents either. But the fact--

Chairman BOEHLERT. People ask me if--

Mr. EHLERS. The fact of the matter is this Nation spent several million dollars, multiple million dollars to prove that there is no cancer risk from electromagnetic radiation from high-power-high-voltage lines, which I decided, after reading-looking at it for two days, decided was the case. But the public wasn't satisfied until we did that, and many still are not satisfied. You could give many other examples of that too.

The public is, I am afraid, irrational on risk issues. And Dr. Bartlett just gave some examples. I can make it even more extreme. About over 100-pardon me-over 1,000 people per day die from cigarette smoking, which is a voluntary choice, and, as far as I can determine, of no benefit whatsoever. And, yet, these same people would be very, very concerned about toxic waste dumps. And I-and at the local level, I remember holding hearings on landfills and solid waste and bleach agent and so forth, and talking afterwards with someone who would then proceed to light a cigarette and drive home in the car, both of which were thousands of times more dangerous than what we had been discussing about the landfill. And that is, unfortunately, what we have to deal with. The public fear of anthrax is immense at this point.

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Now, let me just ask you-let me just propagate a simple theory and ask if you think it is valid. And that is that most of the anthrax cases we have been hearing about have resulted from side contamination from, perhaps, only two letters being directed through the U.S. mail. Recently, just this week, we found evidence of anthrax in the Veterans' Administration mailroom.

I would bet-and this is my theory-that if we examined the mailrooms of virtually all the commercial establishments in this city that we would find anthrax there just as well, in very minute amounts. And, at some point, we simply have to say, look, that is side contamination. It is very, very small. It is not going to infect anyone. It is going to dissipate with time. And it is not worth cleaning up the Veterans' Administration mailroom or Corporation ''X'' mailroom or, perhaps, even perhaps parts of the Ford building that we have closed off, or even a few offices in Longworth that are closed off.

And I think it is absolutely essential that we-that the scientific establishment, as soon as possible, determine reasonable levels of safe exposure to anthrax or safe contamination to anthrax. And it is my understanding that you could have several hundred, perhaps even a thousand anthrax spores in an office and it is very unlikely anyone would get ill from that. Perhaps cutaneous infection, but not likely any more than that. But at-I don't know what the answer is, but I would appreciate your comments on that.

The second question is, you mentioned earlier that the role of the EPA in decontamination should be serving as a public health agency. Is there a public health agency in the Federal Government that really worries-that deals with these things? Every state has a public health agency and they are the locus of responsibility. Is there anything similar in the Federal Government or is it scattered between NIH, the CDC, HHS, EPA, and the Surgeon General? I am with the government, and I don't know. I would appreciate answers. Dr. Goldman.

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Dr. GOLDMAN. Well, let me start out first on your question about really basically-you are right. There needs to be clear decision criteria about what constitutes a level that requires decontamination and what doesn't. Because, as everybody has agreed on this Panel, zero is probably not going to be a possible goal, you know, for any decontamination process. And you do need to have some-it

needs to be science-based decision and you need-we need the application of our knowledge about particles and the statistics of how particles move in buildings which has not been, as far as I can tell, applied to this problem.

Along with that, there is an issue of risk communication, which is also a science. And social scientists will agree with you that there are certain kinds of risks that are unknown, that are dread, that have to do with people attacking us. That-so it is-it doesn't have to do with our personal choice that people are more concerned about than other kinds of risks where they feel that they have a free choice.

And so we need to factor that in, too, in terms of managing the issue, that communications are going to be extremely important and that there are people who have knowledge about that, that can be brought to bear and can be really helpful.

I think that the-your question about, you know, who is-basically it is who is in charge of this kind of problem? And I do think that there is an enormous fragmentation in our public health system, that our Public Health Service doesn't actually exist as a real entity anymore. And so you do have the expertise scattered throughout the government. You have EPA, you have CDC, you have NIH, and you have various experts there who need to be brought together.

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I had suggested that, you know, HHS would be the appropriate coordination focus for this, simply because I think it is-fundamentally, it is a public health issue and that it needs to be there. But right now, there isn't anybody who is clearly in charge, who can clearly direct all of that.

Mr. EHLERS. May I just interrupt a moment? But Secretary Thompson just made an announcement of several appointments today, within HHS, to head up this effort. He established a special effort. So at least that is done. But it is unfortunate-it should have existed before this.

Dr. GOLDMAN. Well, and what we don't know yet is how much authority that Dr. Henderson will have—

Mr. EHLERS. Yes.

Dr. GOLDMAN [continuing]. In terms of actually being able to direct efforts and to coordinate efforts among the different agencies and even the agencies in HHS.

Mr. EHLERS. Yeah. Thank you.

Chairman BOEHLERT. Thank you. Mr. Matheson.

Contamination of Outdoor Sites

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Mr. MATHESON. Thank you, Mr. Chairman. Given recent events, it is clear this hearing is focused primarily on anthrax contamination that has been contained indoors. And, yet, there is some concern in my district about potential terrorist attacks during the Olympic games that are going to be hosted in Salt Lake City. And it has been pointed out how resistant anthrax spores are to-and I think Dr. Goldman's testimony talked about resistant to cold, heat, chemical disinfectants. The question I want to ask the Panel is when looking at bioterrorism and issues of contamination and given the properties of anthrax, is there a potential risk of contamination of an outdoor site?

Dr. BAKER. Yes. I mean, there is no question about that. And, in fact, it could be very problematic because the wind will disseminate in irregular patterns. And I think Sverdlovsk showed that you can have reaerosolization of

outdoor anthrax for many months after it has been released and deposited.

Clearly, DOE is making an effort for the Olympics to set up sort of an archetype sensing system. You know, that-I think there are reasons to presume that they will be able to tell if there is an outdoor release. But control of that release will be very problematic. And certainly, you can't decontaminate a city, you know, as was suggested. You can't try and chase a cloud of something and try and remove it. I mean, there may be ways to seed it out of the air. But, you are right-I mean, it is a major issue. And just documenting that it is there will be a problem.

What was remarkable was that, if I remember correctly, in this briefing, there were background levels of anthrax on some of those detectors, and nobody was blaming Dugway. But certainly, you know, in the ground in the western states, there are anthrax spores. So, you know, the specificity or discerning the difference between a purposeful release and background levels, particularly given the climactic variations that you can have in Utah during that time of the year, will be very much a challenge. But I think, certainly, we should be able to learn from this project also what we might be able to do.

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Mr. MATHESON. Is there-and you mentioned the difficulty if it is an airborne release. But what sort of decontamination efforts could you take or would you want to take at an outdoor venue? Is there even anything you would want to do at that point? And, for example, the opening games are going to be in an outdoor football stadium or the ski jump is an outdoor venue as well.

Dr. BAKER. I will just start off briefly. I think the first thing you want to do is to get as much of the source contained and decontaminated and controlled as possible. Because, if you do that, you prevent dissemination beyond that point. Quite honestly, if you have detected it after dissemination has occurred, there is very little that you can do. And one of the things that we tried to develop with our material was a way to actually try and decontaminate people so that they wouldn't disseminate it.

One of the biggest problems with anthrax spores is that the spores are much tougher than people are, and the efforts-many of the materials to decontaminate them are very toxic and probably would be worse than the minimal levels of contamination these people would have. So I think that is an open question. If you can control the source, that would be the most important part.

Dr. HAAS. You know, and I think in the sort of scenario you are envisioning, even if you had a detector there, by the time the detector detected a signal, likely the exposure to the people would have already occurred. And so there would not be an emergency need to decontaminate because presumably the site could be vacated. But, you know, I think some of the techniques that the various other people have talked about, in terms of surface decontamination and so forth, would come into play.

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Mr. MATHESON. Thank you, Mr. Chairman. I yield back the balance of my time.

Chairman BOEHLERT. Thank you very much. The patient Ms. Hart.

Overuse of Antibacterial Agents and Antibiotics

Ms. HART. Thank you, Mr. Chairman. This is actually extremely interesting, so my patience is really rewarded by being here. I have a question that is a little off the beaten path, but it does apply. And it has to do with sort of commercialization of a lot of things called antibacterial. There has been sort of this fear of bacteria in this country and there has been a great, I guess, marketing tool for a lot of soaps and that sort of thing. As we proceed and try to find ways to fight things like the anthrax Bacillus, are we doing damage to

our ability to fight it by, perhaps, creating other strains of bacteria that would be resistant because of our, maybe what I perceive as overuse of antibacterial agents?

Dr. GOLDMAN. I think that is a question that needs to be researched. And that is both the prophylaxis that has been given and-but also just the-you are right-there is a lot of general use of antibacterials. And could we be creating antibiotic-resistant anthrax on our own by overuse of these things? I think it is a good question.

MS. HART. Could I interrupt for 1 second? Yeah. I agree. And I meant to actually include the fact that so many people were now put on some kind of—

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Dr. GOLDMAN. Right.

Ms. HART [continuing]. Antibiotic.

Dr. GOLDMAN. I think it is an area that needs research.

Dr. BAKER. I think, particularly, in the food industry, that has been one of the greatest sources of antimicrobial-resistant bacteria. And that is not used for any public health or often not for a public health or even an animal health issue. It is used as a growth stimulant. And we need to really redefine antimicrobials. There are many different classes. Some can be used without development of resistance. But the drugs that we use for ourselves need to be kept for ourselves, and even, by physicians, need to be kept for serious infections that really need to be treated with antibiotics.

Dr. HAAS. I actually have been doing work with the soap and detergent industry on some of the antibacterial products. You need to be very careful at distinguishing between the products that are in, you know, the soaps and so forth, and antibiotics that are used in therapy, either in veterinary or in human therapy. Typically, the antibiotics' resistance develops by very specific evolution or selection against mode of action of the antibiotic.

For the household and consumer antimicrobials, those typically are so broad spectrum that there is really no substantial evidence that resistance has evolved. So you need to keep those two separate in your mind.

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Mr. BARBEITO. I have nothing further to add. They have covered it.

Ms. HART. That is okay. Thank you, Mr. Chairman. I yield back.

Chairman BOEHLERT. Thank you very much. I assume you are here for the—

Ms. JACKSON LEE. No. I am here for the questions.

Chairman BOEHLERT. Oh. You are here for the questions. All right. The Chair recognizes Ms. Jackson Lee.

Vulnerability of Ventilation Systems

Ms. JACKSON LEE. Direct question—let me thank you for the hearing. I serve on the Homeland Security Task Force that has been working on a lot of issues dealing with securing our Nation post-September 11. We are gratified that many of you have been working on these issues preceding that. And if there is any statement that can be made, I guess it is a statement of preparedness.

I have a single question regarding the preparedness for ventilation of buildings. And I did hear some of Dr. Baker's testimony. But I would like you to assess the threat dealing with the potential tampering of the ventilation

systems as it relates to anthrax or any others, and the instructions and/or your insight. And I am suggesting the massiveness of buildings across this Nation, which may include our schools, our hospitals.

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Many of the prototypes are ventilation systems that sit open and unprotected on top of buildings, alongside of buildings. And I have been advised and/or briefed on some of the concerns that we should be looking at. Can you assess that as it relates to anthrax or any other potentially inhaled bioterrorism agent and any instructions, whether through science or elsewhere? If all of you could answer that, I would appreciate it. And I have a statement, Mr. Chairman, that I would like to submit into the record, and ask unanimous consent. And I thank the—

Chairman BOEHLERT. Without objection.

MS. JACKSON LEE [continuing]. Ranking Member and the Chairman for holding this hearing.

Dr. HAAS. I will try to give that a start. Generally, HVAC systems have not been designed with an idea to secure them against material that might enter in. You know, I think the one thing that is not clear is the degree to which the ordinary design of HVAC systems in routine buildings may contain various ways for any contaminants to be removed in the normal course of events. And I think that is something that probably needs serious evaluation, as well as potentially retrofitting the HVAC systems in more vulnerable sites for inactivation, to put another barrier, if you will, against intrusion of something that would be added.

MS. JACKSON LEE. Mr. Baker, and also, Dr. Goldman. And in your comments-and I don't want to sort of pose this through you by surprise—but do we learn any lessons from the Legionnaires' incident in Pennsylvania?

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Dr. GOLDMAN. Yes. I was going to mention Legionnaires' disease. I also think you can look at the very high rate of problems with so-called sick buildings, which are often due to poorly maintained HVAC systems and where we have molds and various things in these systems that are going to cause people who have allergies and sensitivities to be sick when they work in them.

So I think that we have had a general neglect, actually, of the maintenance of our buildings, whether they are private buildings or government buildings. And now we are faced with another problem, which is that we have not designed buildings to defend from these new threats. And that this is an issue that needs to be addressed. I would urge that it be addressed in a context of making buildings healthier generally, not just addressing bioterrorism threats, but threats like Legionella and also the contaminants that cause people to have allergies and other reactions when they work in buildings.

Dr. BAKER. As an allergist, this has been a major problem and may be associated with the rise in asthma that we have seen. I think one of the real issues is that we have gone to a system where our buildings are essentially sealed boxes and all the air handling is done through these systems. So there is no way to really try and overcome the one system there, either as a disseminator or as a source of fresh air.

I think those are things that need to be rethought, and I think it is very important. One of the major issues here are countermeasures that make sense not just against biologic terrorism, but improve overall public health. Because if we don't have ongoing biological terrorism, we won't be prepared. People won't be able to maintain, you know, quick fixes for that one purpose. Whereas if these things aid in the general public health of the population, as was suggested, they will more than pay for themselves, as well as help protect us

against terrorism.

Ms. JACKSON LEE. And I thank you very much. You are right about acknowledging the rise in asthma and other allergies that we have seen in the general state of inside air. But as we begin to look across the Nation on how some of our buildings have been constructed, we realize that we do have something else to assess in addition to creating a generally healthy atmosphere for our population. Thank you very much for your questions. I yield back.

Chairman BOEHLERT. Thank you very much. And I do appreciate everyone's indulgence here. And I do appreciate your assistance. And I would ask that-several members have some questions that we might submit to you in writing, and we would greatly appreciate a timely response. We will try not to overburden you, but we do want to learn. But I do want to thank you so much for being with us throughout the morning and being facilitators. You have helped us a great deal. This hearing is now adjourned.

[Whereupon, at 12:30 p.m., the Committee was adjourned.]

Appendix 1:

Biographies, Financial Disclosures, and Reference Material

Next Hearing Segment(2)

(Footnote 1 return)
Microbial inactivation is frequently stated in ''logs''. Each log represents a factor of 10 reduction. So 1 log indicates 90% reduction, 2 logs indicates 99% reduction, etc. The rationale for this is that often (but not always) there is a constant time required for each additional log of inactivation. This is called ''Chick's Law'' (7). So for the results here, assuming Chick's Law, it would require 64.4 = 27 minutes to achieve 6 logs removal.

(Footnote 2 return)
There are a variety of technologies such as use of ascorbic acid, use of reduced iron compounds, or use of reduced sulfur compounds, that exist for this purpose.

(Footnote 3 return)
My comments in this section are focused on agencies outside DOD, since the information with respect to DOD capabilities in the areas of interest are far from clear to individuals outside DOD.

(Footnote 4 return)
Covert, N.M. Cutting Edge, A History of Fort Detrick. 1943-1993 Headquarters, U.S. Army Garrison, Fort Detrick, Frederick, MD. 1st Ed. May 1993, 2nd Ed. 1994

(Footnote 5 return)
References 29 CFR 1910.1048 p418, 29 CFR 1910. 1200(d), and 29 CFR 1910. 1200 appendices A and B

(Footnote 6 return)
Biosafety in Microbiological and Biomedical Laboratories, 4th ed. May 1999
CDC/NIH Us Dept. of Health and Human Services

(Footnote 7 return)
Veterinary Medicine 50 (11) 579-588, Nov. 1955